



524-581





009279901

ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

EPA Receipt Date: JUN 12 2008		EPA Reg. Number: 524-LIR		
	Check List Item	Yes	No	N/A
1	Has the PRIA Fee been Paid ; is a copy of the check or Pay.gov receipt included in the Submission Package?	X		
2	Is an Application Form (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	X		
3	Is a Confidential Statement of Formula (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	X		
4	Is a Formulator's Exemption Statement (EPA Form 8570-27) Included in the Submission Package?		X	
5	Is a Certification with Respect to Citation of Data (EPA Form 8570-34) Included in the Submission Package?	X		
6	Is a Data Matrix (EPA Form 8570-35) Included in the Submission Package?	X		
7	Is a Label Included in the Submission Package?	X		
8	Are Data Included in the Submission Package?	X		
9	Is the Submission an Amendment?		X	

	U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Biopesticides and Pollution Prevention Division (7511P) Ariel Rios Building 1200 Pennsylvania Ave., NW Washington, D.C. 20460	EPA Reg. Number: 524-581	Date of Issuance: JUL 20 2009
		Term of Issuance: Conditional	
		Name of Pesticide Product: MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Insect Protected, Herbicide-Tolerant Corn	
Name and Address of Registrant (include ZIP Code): Monsanto Company 800 North Lindbergh Blvd St. Louis, MO 63167			
Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.			
<p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> <p>This product is conditionally registered in accordance with FIFRA Sec. 3(c)(7)(A) provided you do the following terms and conditions.</p> <ol style="list-style-type: none"> 1) Submit and/or cite all data required for registration/ registration review of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data. 2) The subject registration will automatically expire on midnight November 30, 2011. 3) The subject registration will be limited to MON 89034 x TC1507 x MON 88017 x DAS-59122-7 in field corn. 4) Submit the following data in the time frames listed: 			
Signature of Approving Official: 		Date: 7-20-09	

OPPTS Guideline/ Study Type	Required Data	Due Date
Insect Resistance Management	To address the uncertainty regarding CRW dose and buttress the dose assumptions used in the models, provide additional dose data (using the methods of Storer et al. 2006) with Cry3Bb1 and Cry34/35. Further dose studies could also be conducted with varying egg infestation levels (above and below egg levels expected to trigger density-dependent mortality) to tease out any egg density effects. New techniques to assess CRW dose may need to be pursued as well, if Monsanto/Dow or academic researchers can develop such approaches.	Report Due 11/30/2010
Insect Resistance Management	Monsanto/Dow conducted modeling simulations to investigate the effect of initial resistance allele frequency (RAF). The results from these simulations with a pyramid showed that the initial RAF was insensitive in the model -- the final RAF did not increase significantly from the initial frequency after 10 generations of selection (regardless of the starting value). Nevertheless, BPPD is still concerned that resistance alleles for CRW-targeted Bt traits may be relatively common in the field based on published CRW selection studies (Lefko et al. 2008; Meihls et al. 2008). Monsanto/Dow's modeling has assumed an initial RAF of 0.001. This may be suitable for other pests (e.g. lepidoptera), but BPPD must consider the possibility that actual RAF for CRW is higher (perhaps close to 0.01). To further investigate this issue, resistance selection experiments must be conducted to further characterize the potential for resistance alleles and frequency of occurrence in CRW populations.	Annually First Report Due 11/30/2010
Insect Resistance Management	New model simulations must be conducted to incorporate new data (i.e. from studies conducted under items above) or using possible "worst case" parameters. Although Monsanto/Dow's new model simulations have been more conservative than previous runs, BPPD remains concerned that "worst case" scenarios for SmartStax have not yet been fully investigated. CRW-protected corn is highly adopted in some areas with heavy infestations so that intense selection pressure for resistance can be expected. In light of this, and the large proposed reduction in refuge (from 20% to 5%; a 75% total reduction), BPPD believes that worst case analyses are warranted to help determine the potential for resistance. In particular, model parameters for dose and initial resistance allele frequency could be adjusted to include more conservative estimates (e.g. dose ranges < 94% and RAF > 0.001).	Annually First Report Due 11/30/2010

5) Submit or cite all data required to support the Herculex Xtra and the MON 89034 x MON 88017 stacked plant-incorporated protectant products within the timeframes required by the terms and conditions of EPA Registration Numbers 68467-6 and 524-576.

6) You must commit to do the following Insect Resistance Management Program for MON 89034 x TC1507 x MON 88017 x DAS-59122-7.

The required IRM program for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn must have the following elements:

Requirements relating to creation of a non-*Bt* corn refuge in conjunction with the planting of any acreage of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn;

Requirements for Monsanto to prepare and require MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn users to sign "grower agreements," which impose binding contractual obligations on the grower to comply with the refuge requirements;

Requirements regarding programs to educate growers about IRM requirements;

Requirements regarding programs to evaluate and promote growers' compliance with IRM requirements;

Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1A.105, Cry2Ab2, Cry3Bb1, Cry1F and Cry34Ab1/Cry35Ab1 proteins in the target insects;


Requirements regarding a "remedial action plan," which contains measures Monsanto would take in the event that any field-relevant insect resistance was detected as well as to report on activity under the plan to EPA;

Annual reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreements results, and the compliance assurance program including the educational program on or before January 31st each year, beginning in 2011.

a) Refuge Requirements for MON 89034 x TC1507 x MON 88017 x DAS-59122-7

These refuge requirements do not apply to seed propagation of inbred and hybrid corn seed up to a total of 20,000 acres per county and up to a combined U.S. total of 250,000 acres per PIP active ingredient per registrant per year. Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the following refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

A common refuge must be planted for both corn borers and corn rootworms. The refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn should be sown on the same day, or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties. If the refuge is planted on rotated ground, then the MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn must also be planted on rotated ground. If the combined refuge is planted on continuous corn, the MON 89034 x TC1507 x MON 88017 x DAS-59122-7 field may be planted on either continuous or rotated land (option encouraged where WCRW rotation resistant biotype may be present). Refuge options are based on the planting of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 in cotton or non-cotton growing regions and the insect pressure present in those locations. The



refuge sizes for these regions are either 20% in cotton growing regions (i.e. 20 acres of non-Bt corn for every 80 acres MON 89034 x TC1507 x MON 88017 x DAS-59122-7 planted) or 5% in non-cotton growing regions (5 acres of non-Bt corn for every 95 acres of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 planted). If corn rootworms are significant within a region, the structured refuge must be planted as an in-field or adjacent refuge using corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. It can be planted as a block within or adjacent (e.g., across the road) to the MON 89034 x TC1507 x MON 88017 x DAS-59122-7, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. If insecticides are applied to the refuge for control of CRW adults, the same treatment must also be applied in the same timeframe to MON 89034 x TC1507 x MON 88017 x DAS-59122-7. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). If corn rootworms are not significant within a region, the structured refuge may be planted as an in-field or adjacent refuge or as a separate block that is within 1/2 mile of the MON 89034 x TC1507 x MON 88017 x DAS-59122-7 field. The structured refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

Region	Refuge size	In-field or adjacent refuge is allowed	Refuge separated by up to 1/2 mile is allowed
Cotton growing where CEW is a significant pest and WCRW, NCRW and MCRW are not significant: AR, NC, SC, GA, FL, TN (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton) AL, MS, LA, VA (only the counties of Dinwiddie, Franklin City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex)	20% non-Bt corn	Yes	Yes
Cotton growing where CEW is a significant pest and WCRW, NCRW, and/or MCRW are significant: TX (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and	20% non-Bt corn	Yes	No

Region	Refuge size	In-field or adjacent refuge is allowed	Refuge separated by up to 1/2 mile is allowed
Sherman), OK (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), MO (only the counties of Dunkin, New Madrid, Pemiscot, Scott, and Stoddard).			
Cotton growing where CEW is not a significant pest and WCRW, NCRW and MCRW are not significant: NM, AZ, CA, NV	5% non-Bt corn	Yes	Yes
Non-cotton growing where WCRW, NCRW and MCRW are not significant OR, WA, ID, MT, WY, UT, VA (except the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), WV, PA, MD, DE, CT, RI, NJ, NY, ME, MA, NH, VT, HI, AK, TN(except the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton)	5% non-Bt corn	Yes	Yes
Non-cotton growing where WCRW, NCRW and/or MCRW are significant: KS, NE, SD, ND, MN, IA, MO (except the counties of Dunkin, New Madrid, Pemiscot, Scott, and Stoddard), IL, WI, MI, IN, OH, KY, CO, OK (except the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), TX (only the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman)	5% non-Bt corn	Yes	No

b) Grower Agreement for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Corn

1) Persons purchasing MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.

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- 2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3) Monsanto must implement a system (equivalent to what is already approved for previously registered Monsanto *Bt* corn products), which is reasonably likely to assure that persons purchasing *MON 89034 x TC1507 x MON 88017 x DAS-59122-7* corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program. A description of the system must be submitted to EPA within 90 days from the date of registration.
- 4) Monsanto must use a grower agreement and must submit to EPA, within 90 days from the date of registration, a copy of that agreement and any specific stewardship documents referenced in the grower agreement. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, 30 days prior to implementing a proposed change, Monsanto must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this registration.
- 5) Monsanto must implement a system (equivalent to what is already approved for previously registered Monsanto *Bt* corn products), which is reasonably likely to assure that persons purchasing *MON 89034 x TC1507 x MON 88017 x DAS-59122-7* corn sign grower agreement(s). A description of the system must be submitted to EPA within 90 days from the date of registration.
- 6) Monsanto shall maintain records of all *MON 89034 x TC1507 x MON 88017 x DAS-59122-7* corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
- 7) Beginning on January 31, 2011 and annually thereafter, Monsanto shall provide EPA with a report on the number of units of *MON 89034 x TC1507 x MON 88017 x DAS-59122-7* corn seed shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of a twelve-month period. Note: The first report shall contain the specified information from the time frame starting with the date of registration and extending through the 2010 growing season.
- 8) Monsanto must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c) IRM Education and IRM Compliance Monitoring Program for *MON 89034 x TC1507 x MON 88017 x DAS-59122-7* Corn

- 1) Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to *MON 89034 x TC1507 x MON 88017 x DAS-59122-7* corn users the

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importance of complying with the IRM program. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by internet, radio, or television commercials. Copies of the materials will be provided to EPA for their records. The program shall involve at least one written communication annually to each MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education program with the educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.

2) Annually, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3) Beginning January 31, 2011, Monsanto must provide a report to EPA summarizing the activities it carried out under its education program for the prior year. Annually thereafter, Monsanto must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Monsanto must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC).

4) Given that MON 89034 x TC1507 x MON 88017 x DAS-59122-7 will likely have different refuge strategies for lepidoptera and CRW than other registered Bt corn products, you must submit a revised compliance assurance program (CAP) within 90 days of the date of registration. This revised CAP must be found acceptable by BPPD by April 1, 2010. This strategy should be specific for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 and the new refuge requirements. Availability of non-Bt corn refuge seeds in desirable varieties must be addressed. Compliance is an area of ongoing concern -- recent data have shown that refuge compliance for Bt corn has fallen in recent years.

d) Insect Resistance Monitoring and Remedial Action Plans for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Corn

Existing programs for resistance monitoring and remedial action that were established for MON 89034 (Cry1A.105 and Cry2Ab2), MON 88017 (Cry3Bb1), and Herculex Xtra (Cry1F and Cry34/35) should be applicable to MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn. In light of potentially lower overall structured Bt corn structured refuge, the CRW resistance monitoring program must be expanded (i.e. with additional sampling and collection sites or improved monitoring techniques). Also, a revised definition of "resistance" may be needed for the CRW monitoring and remedial action plans based on recent research and selection experiments (Lefko et al. 2008; Meihls et al. 2008). You must submit a revised resistance monitoring and remedial action plan within 90 days of the date of registration that must be found acceptable to BPPD by April 1, 2010.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year, beginning in 2011, for the duration of the conditional registration.

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e) Annual Reporting Requirements for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Corn

- 1) Annual Sales: reported and summed by state (county level data available by request) January 31st each year, beginning in 2011;
- 2) Grower Agreements: number of units of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn seed shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year, beginning in 2011;
- 3) Grower Education: substantive changes to education program completed previous year, January 31st each year, beginning in 2011;
- 4) Compliance Assurance Program: compliance assurance program activities and results for the prior year and plans for the compliance assurance program for the current year, January 31st each year, beginning in 2011;
- 5) Compliance Survey Results: results of annual surveys for the prior year and survey plans for the current year; full report January 31st each year, beginning in 2011;
- 6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year, beginning in 2011.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA Section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A copy of the stamped label is enclosed for your records.

Sincerely,



W. Michael McDavit, Acting Director
Biopesticides and Pollution
Prevention Division (7511P)

Enclosure

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Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

Insect-Protected, Herbicide-Tolerant Corn

(Alternate brand name: Genuity™ SmartStax™)

(OECD Unique Identifier: MON-89034-3 × DAS-Ø1507-1 × MON-88017-3 × DAS-59122-7)

Active Ingredients:

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034.....≤ 0.0026%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034≤ 0.0053%*

Bacillus thuringiensis Cry1F protein and the genetic material necessary (vector PHP8999) for its production in corn event TC1507≤ 0.0012%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017.....≤ 0.0079%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material necessary (vector PHP17662) for its production in corn event DAS-59122-7.....≤ 0.0194%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material necessary (vector PHP17662) for its production in corn event DAS-59122-7.....≤ 0.0042%*

Inert Ingredients:

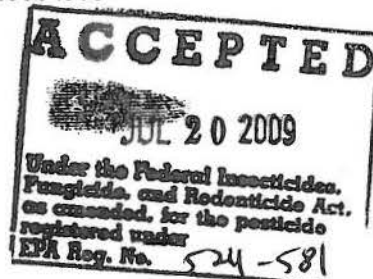
CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017≤ 0.0052%*

PAT protein (phosphinothricin acetyl transferase) and the genetic material necessary (vectors PHP17622 and PHP8999) for its production in corn event TC1507 and DAS-59122-7...≤ 0.00045%*

*Maximum percent (wt/wt) of dry forage

CAUTION

Monsanto Company



07-CR-192E-1

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KEEP OUT OF REACH OF CHILDREN

NET CONTENTS _____

EPA Registration No. 524-581

EPA Establishment No. 524-MO-002

EPA Establishment No. 029964-LA-001

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this ^{product} ~~seed~~ in any manner inconsistent with ^{its} ~~this~~ labeling.
Information regarding commercial production must be included in the Technology Use Guide.

MON 89034 × TC1507 × DAS-59122-7 × MON 88017 protects corn crops from leaf, stalk, and ear damage caused by corn borers and root damage caused by corn rootworm larvae. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × DAS-59122-7 × MON 88017 corn, an insect resistance management plan must be implemented which includes planting of a structured refuge. Growers who fail to comply with the IRM requirements risk losing access to Monsanto's corn PIP products.

These refuge requirements do not apply to seed propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined US total of 250,000 acres per PIP active ingredient per year.

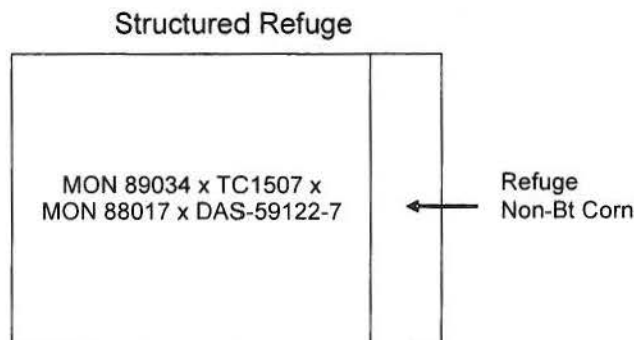
Several options for deployment of the refuge for MON 89034 × TC1507 × DAS-59122-7 × MON 88017 are available to growers. These options are based on the planting of MON 89034 × TC1507 × DAS-59122-7 × MON 88017 in cotton or non-cotton growing regions and the insect pressure present in those locations. The refuge sizes for these regions are either 5% (i.e. 5 acres of non-Bt corn for every 95 acres MON 89034 × TC1507 × DAS-59122-7 × MON 88017 planted) or 20% (20 acres of non-Bt corn for every 80 acres of MON 89034 × TC1507 × DAS-59122-7 × MON 88017 planted), and are presented in the table below:

Region	Refuge size	In-field or adjacent refuge allowed	Refuge separated by up to ½ mile allowed
Cotton growing where CEW is a significant pest and WCRW, NCRW and MCRW are not significant: NC, SC, GA, FL, TN (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), AL, MS, LA, AR, VA (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex)	20% non-Bt corn	Yes	Yes
Cotton growing where CEW is a significant pest and WCRW, NCRW, and/or MCRW are significant: TX (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), OK (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), MO (only the counties of Dunkin, New Madrid, Pemiscot, Scott, and Stoddard)	20% non-Bt corn	Yes	No
Cotton growing where CEW is not a significant pest and WCRW, NCRW and MCRW are not significant: NM, AZ, CA, NV	5% non-Bt corn	Yes	Yes
Non-cotton growing where WCRW, NCRW and MCRW are not significant: OR, WA, ID, MT, WY, UT, VA (except the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton,	5% non-Bt corn	Yes	Yes

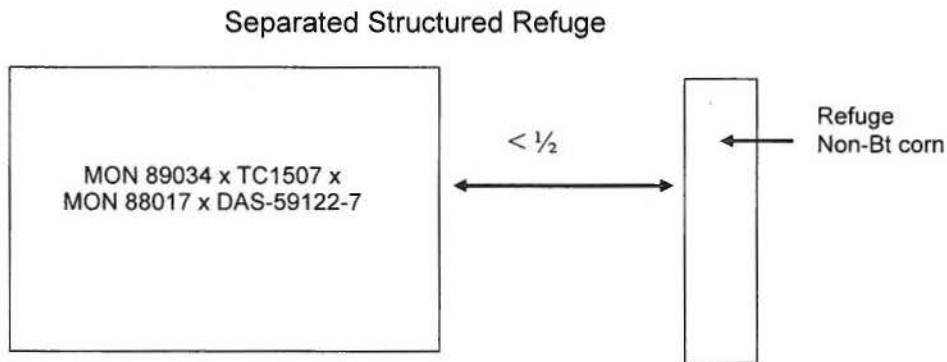
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Southampton, Suffolk City, Surrey, and Sussex), WV, PA, MD, DE, CT, RI, NJ, NY, ME, MA, NH, VT, HI, AK, TN (except the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton)			
Non-cotton-growing where WCRW, NCRW and/or MCRW are significant: KS, NE, SD, ND, MN, IA, MO (except the counties of Dunkin, New Madrid, Pemiscot, Scott, and Stoddard), IL, WI, MI, IN, OH, KY, CO, OK (except the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), TX (only the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman)	5% non-Bt corn	Yes	No

If corn rootworms are significant within a region, the structured refuge must be planted as an in-field or adjacent refuge using corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. It can be planted as a block within or adjacent (e.g., across the road) to the MON 89034 × TC1507 × MON 88017 × DAS-59122-7, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). A schematic of one common refuge deployment option is shown below:



If corn rootworms are not significant within a region, the structured refuge may be planted as an in-field or adjacent refuge, or as a separate block that is within ½ mile of the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 field. The structured refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). A schematic of one refuge option with the refuge planted within a ½ mile of the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 field is shown below:



Corn Insects Controlled or Suppressed

European corn borer (ECB)
 Southwestern corn borer (SWCB)
 Southern cornstalk borer (SCSB)
 Corn earworm (CEW)
 Fall armyworm (FAW)
 Stalk borer
 Lesser corn stalk borer
 Sugarcane borer (SCB)
 Western bean cutworm (WBC)
 Black cutworm

Ostrinia nubilalis
Diatraea grandiosella
Diatraea crambidoides
Helicoverpa zea
Spodoptera frugiperda
Papaipema nebris
Elasmopalpus lignosellus
Diatraea saccharalis
Richia albicosta
Agrotis ipsilon

Western corn rootworm (WCRW)
 Northern corn rootworm (NCRW)
 Mexican corn rootworm (MCRW)

Diabrotica virgifera virgifera
Diabrotica barberi
Diabrotica virgifera zea

Sales of corn hybrids that contain Monsanto's Bt corn plant pesticide must be accompanied by a Grower Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5023179, 5110732, 5164316, 5196525, 5322938, 5352605, 5359142, 5378619, 5424412, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6962705, 7064249, 7227056, and 7250501.

EPA Accepted: __/__/__



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution
Prevention Division (7511P)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

EPA Reg. Number:

524-581

Date of Issuance:

JUL 20 2009

Term of Issuance: Conditional

Name of Pesticide Product:

MON 89034 x TC1507 x MON
 88017 x DAS-59122-7 Insect
 Protected, Herbicide-Tolerant
 Corn

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
 (under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Monsanto Company
 800 North Lindbergh Blvd
 St. Louis, MO 63167

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA Sec. 3(c)(7)(A) provided you do the following terms and conditions.

- 1) Submit and/or cite all data required for registration/ registration review of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
- 2) The subject registration will automatically expire on midnight November 30, 2011.
- 3) The subject registration will be limited to MON 89034 x TC1507 x MON 88017 x DAS-59122-7 in field corn.
- 4) Submit the following data in the time frames listed:

Signature of Approving Official:			CONCURRENCES			Date:		
SYMBOL	7511P	7511P	7511P					
SURNAME	Reynolds	Reynolds	Rueh					116
DATE	7/20/09	7/20/09	7/20/09					

OPPTS Guideline/ Study Type	Required Data	Due Date
Insect Resistance Management	To address the uncertainty regarding CRW dose and buttress the dose assumptions used in the models, provide additional dose data (using the methods of Storer et al. 2006) with Cry3Bb1 and Cry34/35. Further dose studies could also be conducted with varying egg infestation levels (above and below egg levels expected to trigger density-dependent mortality) to tease out any egg density effects. New techniques to assess CRW dose may need to be pursued as well, if Monsanto/Dow or academic researchers can develop such approaches.	Report Due 11/30/2010
Insect Resistance Management	Monsanto/Dow conducted modeling simulations to investigate the effect of initial resistance allele frequency (RAF). The results from these simulations with a pyramid showed that the initial RAF was insensitive in the model -- the final RAF did not increase significantly from the initial frequency after 10 generations of selection (regardless of the starting value). Nevertheless, BPPD is still concerned that resistance alleles for CRW-targeted Bt traits may be relatively common in the field based on published CRW selection studies (Lefko et al. 2008; Meihls et al. 2008). Monsanto/Dow's modeling has assumed an initial RAF of 0.001. This may be suitable for other pests (e.g. lepidoptera), but BPPD must consider the possibility that actual RAF for CRW is higher (perhaps close to 0.01). To further investigate this issue, resistance selection experiments must be conducted to further characterize the potential for resistance alleles and frequency of occurrence in CRW populations.	Annually First Report Due 11/30/2010
Insect Resistance Management	New model simulations must be conducted to incorporate new data (i.e. from studies conducted under items above) or using possible "worst case" parameters. Although Monsanto/Dow's new model simulations have been more conservative than previous runs, BPPD remains concerned that "worst case" scenarios for SmartStax have not yet been fully investigated. CRW-protected corn is highly adopted in some areas with heavy infestations so that intense selection pressure for resistance can be expected. In light of this, and the large proposed reduction in refuge (from 20% to 5%; a 75% total reduction), BPPD believes that worst case analyses are warranted to help determine the potential for resistance. In particular, model parameters for dose and initial resistance allele frequency could be adjusted to include more conservative estimates (e.g. dose ranges < 94% and RAF > 0.001).	Annually First Report Due 11/30/2010

5) Submit or cite all data required to support the Herculex Xtra and the MON 89034 x MON 88017 stacked plant-incorporated protectant products within the timeframes required by the terms and conditions of EPA Registration Numbers 68467-6 and 524-576.

6) You must commit to do the following Insect Resistance Management Program for MON 89034 x TC1507 x MON 88017 x DAS-59122-7.

The required IRM program for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn must have the following elements:

Requirements relating to creation of a non-*Bt* corn refuge in conjunction with the planting of any acreage of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn;

Requirements for Monsanto to prepare and require MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn users to sign "grower agreements," which impose binding contractual obligations on the grower to comply with the refuge requirements;

Requirements regarding programs to educate growers about IRM requirements;

Requirements regarding programs to evaluate and promote growers' compliance with IRM requirements;

Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1A.105, Cry2Ab2, Cry3Bb1, Cry1F and Cry34Ab1/Cry35Ab1 proteins in the target insects;

Requirements regarding a "remedial action plan," which contains measures Monsanto would take in the event that any field-relevant insect resistance was detected as well as to report on activity under the plan to EPA;

Annual reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreements results, and the compliance assurance program including the educational program on or before January 31st each year, beginning in 2011.

a) Refuge Requirements for MON 89034 x TC1507 x MON 88017 x DAS-59122-7

These refuge requirements do not apply to seed propagation of inbred and hybrid corn seed up to a total of 20,000 acres per county and up to a combined U.S. total of 250,000 acres per PIP active ingredient per registrant per year. Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the following refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

A common refuge must be planted for both corn borers and corn rootworms. The refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn should be sown on the same day, or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties. If the refuge is planted on rotated ground, then the MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn must also be planted on rotated ground. If the combined refuge is planted on continuous corn, the MON 89034 x TC1507 x MON 88017 x DAS-59122-7 field may be planted on either continuous or rotated land (option encouraged where WCRW rotation resistant biotype may be present). Refuge options are based on the planting of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 in cotton or non-cotton growing regions and the insect pressure present in those locations. The

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refuge sizes for these regions are either 20% in cotton growing regions (i.e. 20 acres of non-Bt corn for every 80 acres MON 89034 x TC1507 x MON 88017 x DAS-59122-7 planted) or 5% in non-cotton growing regions (5 acres of non-Bt corn for every 95 acres of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 planted). If corn rootworms are significant within a region, the structured refuge must be planted as an in-field or adjacent refuge using corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. It can be planted as a block within or adjacent (e.g., across the road) to the MON 89034 x TC1507 x MON 88017 x DAS-59122-7, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. If insecticides are applied to the refuge for control of CRW adults, the same treatment must also be applied in the same timeframe to MON 89034 x TC1507 x MON 88017 x DAS-59122-7. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). If corn rootworms are not significant within a region, the structured refuge may be planted as an in-field or adjacent refuge or as a separate block that is within 1/2 mile of the MON 89034 x TC1507 x MON 88017 x DAS-59122-7 field. The structured refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

Region	Refuge size	In-field or adjacent refuge is allowed	Refuge separated by up to 1/2 mile is allowed
Cotton growing where CEW is a significant pest and WCRW, NCRW and MCRW are not significant: AR, NC, SC, GA, FL, TN (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton) AL, MS, LA, VA (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex)	20% non-Bt corn	Yes	Yes
Cotton growing where CEW is a significant pest and WCRW, NCRW, and/or MCRW are significant: TX (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and	20% non-Bt corn	Yes	No

Region	Refuge size	In-field or adjacent refuge is allowed	Refuge separated by up to 1/2 mile is allowed
Sherman), OK (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), MO (only the counties of Dunkin, New Madrid, Pemiscot, Scott, and Stoddard).			
Cotton growing where CEW is not a significant pest and WCRW, NCRW and MCRW are not significant: NM, AZ, CA, NV	5% non-Bt corn	Yes	Yes
Non-cotton growing where WCRW, NCRW and MCRW are not significant OR, WA, ID, MT, WY, UT, VA (except the counties of Dinwiddie, Franklin City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), WV, PA, MD, DE, CT, RI, NJ, NY, ME, MA, NH, VT, HI, AK, TN(except the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton)	5% non-Bt corn	Yes	Yes
Non-cotton growing where WCRW, NCRW and/or MCRW are significant: KS, NE, SD, ND, MN, IA, MO (except the counties of Dunkin, New Madrid, Pemiscot, Scott, and Stoddard), IL, WI, MI, IN, OH, KY, CO, OK (except the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), TX (only the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman)	5% non-Bt corn	Yes	No

b) Grower Agreement for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Corn

1) Persons purchasing MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.

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- 2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3) Monsanto must implement a system (equivalent to what is already approved for previously registered Monsanto *Bt* corn products), which is reasonably likely to assure that persons purchasing MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program. A description of the system must be submitted to EPA within 90 days from the date of registration.
- 4) Monsanto must use a grower agreement and must submit to EPA, within 90 days from the date of registration, a copy of that agreement and any specific stewardship documents referenced in the grower agreement. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, 30 days prior to implementing a proposed change, Monsanto must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this registration.
- 5) Monsanto must implement a system (equivalent to what is already approved for previously registered Monsanto *Bt* corn products), which is reasonably likely to assure that persons purchasing MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn sign grower agreement(s). A description of the system must be submitted to EPA within 90 days from the date of registration.
- 6) Monsanto shall maintain records of all MON 89034 x TC1507x MON 88017 x DAS-59122-7 corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
- 7) Beginning on January 31, 2011 and annually thereafter, Monsanto shall provide EPA with a report on the number of units of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn seed shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of a twelve-month period. Note: The first report shall contain the specified information from the time frame starting with the date of registration and extending through the 2010 growing season.
- 8) Monsanto must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c) IRM Education and IRM Compliance Monitoring Program for MON 89034 x TC1507 x MON 88017 x DAS-59122-7Corn

- 1) Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn users the

importance of complying with the IRM program. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by internet, radio, or television commercials. Copies of the materials will be provided to EPA for their records. The program shall involve at least one written communication annually to each MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education program with the educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.

2) Annually, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3) Beginning January 31, 2011, Monsanto must provide a report to EPA summarizing the activities it carried out under its education program for the prior year. Annually thereafter, Monsanto must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Monsanto must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC).

4) Given that MON 89034 x TC1507 x MON 88017 x DAS-59122-7 will likely have different refuge strategies for lepidoptera and CRW than other registered Bt corn products, you must submit a revised compliance assurance program (CAP) within 90 days of the date of registration. This revised CAP must be found acceptable by BPPD by April 1, 2010. This strategy should be specific for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 and the new refuge requirements. Availability of non-Bt corn refuge seeds in desirable varieties must be addressed. Compliance is an area of ongoing concern -- recent data have shown that refuge compliance for Bt corn has fallen in recent years.

d) Insect Resistance Monitoring and Remedial Action Plans for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Corn

Existing programs for resistance monitoring and remedial action that were established for MON 89034 (Cry1A.105 and Cry2Ab2), MON 88017 (Cry3Bb1), and Herculex Xtra (Cry1F and Cry34/35) should be applicable to MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn. In light of potentially lower overall structured Bt corn structured refuge, the CRW resistance monitoring program must be expanded (i.e. with additional sampling and collection sites or improved monitoring techniques). Also, a revised definition of "resistance" may be needed for the CRW monitoring and remedial action plans based on recent research and selection experiments (Lefko et al. 2008; Meihls et al. 2008). You must submit a revised resistance monitoring and remedial action plan within 90 days of the date of registration that must be found acceptable to BPPD by April 1, 2010.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year, beginning in 2011, for the duration of the conditional registration.

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e) Annual Reporting Requirements for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Corn

- 1) Annual Sales: reported and summed by state (county level data available by request) January 31st each year, beginning in 2011;
- 2) Grower Agreements: number of units of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn seed shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year, beginning in 2011;
- 3) Grower Education: substantive changes to education program completed previous year, January 31st each year, beginning in 2011;
- 4) Compliance Assurance Program: compliance assurance program activities and results for the prior year and plans for the compliance assurance program for the current year, January 31st each year, beginning in 2011;
- 5) Compliance Survey Results: results of annual surveys for the prior year and survey plans for the current year; full report January 31st each year, beginning in 2011;
- 6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year, beginning in 2011.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA Section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A copy of the stamped label is enclosed for your records.

Sincerely,



W. Michael McDavit, Acting Director
Biopesticides and Pollution
Prevention Division (7511P)

Enclosure



MONSANTO



July 16, 2009

MONSANTO COMPANY
800 NORTH LINDBERGH BLVD.
ST. LOUIS, MISSOURI 63167
<http://www.monsanto.com>

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: Sheryl Reilly, PhD

Chief, Microbial Pesticides Branch, Biopesticide and Pollution Prevention Division
(7511P)

Subject: Pre-Acceptance letter Regarding June 11, 2008 Application to Register
MON 89034 × TC1507 × MON 88017 × DAS-59122-7

EPA Registration Number: 524-LIR

Dear Dr. Reilly:

This letter is responding to the EPA's July 15, 2009 pre-acceptance letter regarding Monsanto Company's application to register MON 89034 × TC1507 × MON 88017 × DAS-59122-7. In order to support completion of the registration, we are providing this response and attaching a revised label as requested. Monsanto agrees with the points in the July 15, 2009 pre-acceptance letter and accepts all the proposed conditions for registration, with the following proposed changes:

EPA July 15 letter (points):

(1-3) Agree

(4) Agree, a revised label is attached to this letter, Attachment 1.

(5) Page 2, the Confidential Attachment referenced in Monsanto's April 9, 2009 letter contains company confidential responses to EPA's questions which would significantly advantage competitors. However the category of that letter's attachment should be amended to classify as confidential category "B", Information that can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g), Attachment 2.

Monsanto Company

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Document	Category
Response to EPA Letter of April 9, 2009	B

(6) Agree. Label amendments will be submitted by separate letter.

(7) Agree and add the following proposed change: Second study final sentence, change "...experiments must be conducted to further characterize putative resistance alleles and frequency of occurrence in CRW populations." to "...experiments must be conducted to further characterize **the potential for** resistance alleles and frequency of occurrence in CRW populations."

(8) Agree

(9) Agree and add the following proposed changes

- Bottom of page 3, change "...Cry1A.105, Cry2Ab2, Cry3A, Cry1F ...", to "...Cry1A.105, Cry2Ab2, **Cry3Bb1**, Cry1F
- Subsection "a", second paragraph, sentence 4, page 4: change: "...are either 5% in cotton growing regions (i.e. 5 acres of non-Bt corn for every 95 acres MON 89034 × TC1507 × MON 88017 × DAS-59122-7 planted) or 20% in non-cotton growing regions..." TO "...are either 5% in **non-cotton** growing areas (i.e. 5 acres of non-Bt corn for every 95 acres MON 89034 × TC1507 × MON 88017 × DAS-59122-7 planted) or 20% in **cotton** growing regions..."
- Small changes to the growing regions table are clarified in the attached revised label. Notably
 - AR was moved from the second category row from the top, to the first category based on the distribution maps of CRW, (western and Mexican CRW in particular) in ESA's "Handbook of Corn Insects" and information from state extension websites, either WCRW or MCRW is absent from AR.
 - The third category was divided without otherwise changing text into cotton growing areas and non-cotton growing areas.
 - The third and forth columns were clarified by addition of the word "allowed".
- Subsection "b", point 4, page 6: change first sentence from "Monsanto must use an approved grower agreement and must submit to EPA, within 90 days from the date of registration, a copy of that agreement ..." to "Monsanto must use a grower agreement and must submit to EPA, within 90 days from the date of registration, a copy of that agreement ..."
- Subsection "b", point 5, page 6: change first sentence from "Monsanto must implement an approved system..." to "Monsanto must implement a system..."
- Subsection "e", point 2, page 8: The reporting requirements for number of units of seed shipped was changed from January 31st 2010, to January 31st, 2011.

This letter includes one attachment that is classified as category "A" Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.

Document	Category
Label for MON 89034 × TC1507 × MON 88017 × DAS-59122-7	A

If you have any questions regarding this response letter, please do not hesitate to contact Dr. Russell Schneider at 202-383-2866 or myself at 314-694-6514.

Sincerely,



J. Austin Burns, Ph.D.

Regulatory Affairs Manager, Monsanto Company

cc: Mr. Mike Mendelsohn, EPA BPPD
Dr. Russell Schneider, Monsanto Company
Mr.. Brad Shurdut, Dow AgroSciences, LLC
Ms. Laura Tagliani, Dow AgroSciences, LLC

Attachments:

- (1) Revised label for MON 89034 × TC1507 × MON 88017 × DAS-59122-7
- (2) Justification of confidential claims for the Confidential Attachment to in the April 9 letter

Attachment 1

Plant-Incorporated Protectant Label

MON 89034 \times TC1507 \times MON 88017 \times DAS-59122-7

Monsanto Company

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Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

Insect-Protected, Herbicide-Tolerant Corn

(Alternate brand name: Genuity™ SmartStax™)

(OECD Unique Identifier: MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7)

Active Ingredients:

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034.....≤ 0.0026%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034≤ 0.0053%*

Bacillus thuringiensis Cry1F protein and the genetic material necessary (vector PHP8999) for its production in corn event TC1507≤ 0.0012%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017.....≤ 0.0079%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material necessary (vector PHP17662) for its production in corn event DAS-59122-7..... ≤ 0.0194%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material necessary (vector PHP17662) for its production in corn event DAS-59122-7..... ≤ 0.0042%*

Inert Ingredients:

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017≤ 0.0052%*

PAT protein (phosphinothricin acetyl transferase) and the genetic material necessary (vectors PHP17622 and PHP8999) for its production in corn event TC1507 and DAS-59122-7..≤ 0.00045%*

*Maximum percent (wt/wt) of dry forage

CAUTION

KEEP OUT OF REACH OF CHILDREN

Monsanto Company

07-CR-192E-1

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NET CONTENTS _____

EPA Registration No. 524-581

EPA Establishment No. 524-MO-002

EPA Establishment No. 029964-1A-001

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling. Information regarding commercial production must be included in the Technology Use Guide.

MON 89034 × TC1507 × DAS-59122-7 × MON 88017 protects corn crops from leaf, stalk, and ear damage caused by corn borers and root damage caused by corn rootworm larvae. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × DAS-59122-7 × MON 88017 corn, an insect resistance management plan must be implemented which includes planting of a structured refuge. Growers who fail to comply with the IRM requirements risk losing access to Monsanto's corn PIP products.

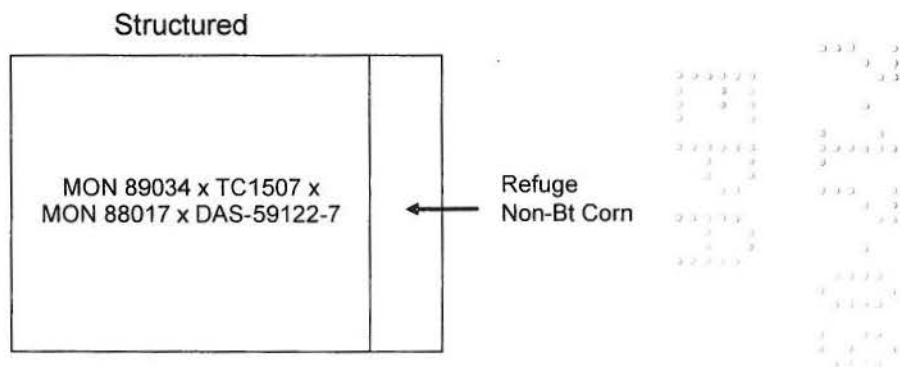
These refuge requirements do not apply to seed propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined US total of 250,000 acres per PIP active ingredient per year.

Several options for deployment of the refuge for MON 89034 × TC1507 × DAS-59122-7 × MON 88017 are available to growers. These options are based on the planting of MON 89034 × TC1507 × DAS-59122-7 × MON 88017 in cotton or non-cotton growing regions and the insect pressure present in those locations. The refuge sizes for these regions are either 5% (i.e. 5 acres of non-Bt corn for every 95 acres MON 89034 × TC1507 × DAS-59122-7 × MON 88017 planted) or 20% (20 acres of non-Bt corn for every 80 acres of MON 89034 × TC1507 × DAS-59122-7 × MON 88017 planted), and are presented in the table below:

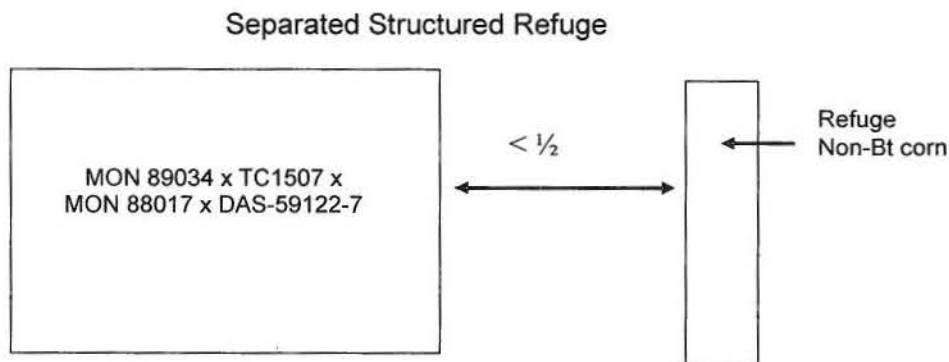
Region	Refuge size	In-field or adjacent refuge allowed	Refuge separated by up to ½ mile allowed
Cotton growing where CEW is a significant pest and WCRW, NCRW and MCRW are not significant: NC, SC, GA, FL, TN (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), AL, MS, LA, AR, VA (only the counties of Dinwiddie, Franklin City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex)	20% non-Bt corn	Yes	Yes
Cotton growing where CEW is a significant pest and WCRW, NCRW, and/or MCRW are significant: TX (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), OK (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), MO (only the counties of Dunkin, New Madrid, Pemiscot, Scott, and Stoddard)	20% non-Bt corn	Yes	No
Cotton growing where CEW is not a significant pest and WCRW, NCRW and MCRW are not significant: NM, AZ, CA, NV	5% non-Bt corn	Yes	Yes
Non-cotton growing where WCRW, NCRW and MCRW are not significant: OR, WA, ID, MT, WY, UT, VA (except the counties of Dinwiddie, Franklin City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), WV, PA, MD, DE, CT, RI, NJ,	5% non-Bt corn	Yes	Yes

NY, ME, MA, NH, VT, HI, TN (except the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton)			
Non-cotton-growing where WCRW, NCRW and/or MCRW are significant: KS, NE, SD, ND, MN, IA, MO (except the counties of Dunkin, New Madrid, Pemiscot, Scott, and Stoddard), IL, WI, MI, IN, OH, KY, CO, OK (except the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), TX (only the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman)	5% non-Bt corn	Yes	No

If corn rootworms are significant within a region, the structured refuge must be planted as an in-field or adjacent refuge using corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. It can be planted as a block within or adjacent (e.g., across the road) to the MON 89034 × TC1507 × MON 88017 × DAS-59122-7, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). A schematic of one common refuge deployment option is shown below:



If corn rootworms are not significant within a region, the structured refuge may be planted as an in-field or adjacent refuge, or as a separate block that is within ½ mile of the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 field. The structured refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). A schematic of one refuge option with the refuge planted within a ½ mile of the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 field is shown below:



Corn Insects Controlled or Suppressed

European corn borer (ECB)
 Southwestern corn borer (SWCB)
 Southern cornstalk borer (SCSB)
 Corn earworm (CEW)
 Fall armyworm (FAW)
 Stalk borer
 Lesser corn stalk borer
 Sugarcane borer (SCB)
 Western bean cutworm (WBC)
 Black cutworm

Ostrinia nubilalis
Diatraea grandiosella
Diatraea crambidoides
Helicoverpa zea
Spodoptera frugiperda
Papaipema nebris
Elasmopalpus lignosellus
Diatraea saccharalis
Richia albicosta
Agrotis ipsilon

Western corn rootworm (WCRW)
 Northern corn rootworm (NCRW)
 Mexican corn rootworm (MCRW)

Diabrotica virgifera virgifera
Diabrotica barberi
Diabrotica virgifera zeae

Sales of corn hybrids that contain Monsanto's Bt corn plant pesticide must be accompanied by a Grower Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5023179, 5110732, 5164316, 5196525, 5322938, 5352605, 5359142, 5378619, 5424412, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6962705, 7064249, 7227056, and 7250501.

EPA Accepted: __/__/__

07-CR-192E-1

Attachment 2

Confidential Claims Justification for the ‘Confidential Attachment’ in the April 9, 2009 response to EPA’s letter of March 19, 2009

Monsanto Company

07-CR-192E-1

34

Page _____ is not included in this copy.

Pages 35 through 36 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
 - ☐ Identity of product impurities.
 - ☐ Description of the product manufacturing process.
 - ☐ Description of quality control procedures.
 - ☐ Identity of the source of product ingredients.
 - ☐ Sales or other commercial/financial information.
 - ☐ A draft product label.
 - ☐ The product confidential statement of formula.
 - ☐ Information about a pending registration action.
 - ☐ FIFRA registration data.
 - ☐ The document is a duplicate of page(s) _____.
 - ☐ The document is not responsive to the request.
 - ☐ Proprietary information pertaining to the chemical composition of an inert ingredient provided by the source of the ingredient.
 - ☐ Attorney-Client Privilege.
 - ☒ Claimed Confidential by submitter upon submission to the Agency.
 - ☐ Internal Deliberative Information.
-

* The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

JUL 15 2009

Dr. J. Austin Burns
Regulatory Affairs Manager
Monsanto Company
800 North Lindbergh Blvd
St. Louis, MO 63167

Dear Dr. Burns:

Subject: Pre-Acceptance Letter Regarding Your June 11, 2008 Application to Register MON 89034 x TC1507 x MON 88017 x DAS-59122-7
EPA Registration No. 524-LIR

This is a pre-acceptance letter regarding Monsanto Company's application to register the above referenced product for a Section 3 registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Environmental Protection Agency (EPA) will consider registering Monsanto Company's MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn product under FIFRA Section 3(c)(7)(A) provided Monsanto Company amends its application by submitting the required information as described in this letter.

This letter does not constitute a commitment to register the subject product, nor is it intended to imply that EPA will register the subject product. Rather, the purpose of this letter is to inform you that, if Monsanto Company submits the information in writing as described in this letter, EPA will be able to continue to process the registration application in accordance with our normal procedures.

Thus, to enable us to continue to process the subject registration application, EPA requests that the Monsanto Company do or agree in writing to the following.

- 1) The subject registration will automatically expire on midnight November 31, 2011.
- 2) The subject registration will be limited to MON 89034 x TC1507 x MON 88017 x DAS-59122-7 in field corn.
- 3) The registrant must submit/cite all data required for registration of their products under FIFRA §3(c)(5) when the Agency requires registrants of similar products to submit such data.

		CONCURRENCES					
SYMBOL	25118	75118					
SURNAME	Mander	Rey					27
DATE	7/16/09	7-15-09					

- 4) Submit a revised product label incorporating the IRM refuge requirements outlined further in this letter,
- 5) Withdraw your claims of confidentiality for the Confidential Attachment to your April 9, 2009 letter or provide adequate substantiation for the claim.
- 6) Both the Herculex Xtra (EPA Reg. No. 68467-6) and the MON 89034 x MON 88017 (EPA Reg. No. 524-576) registrations must be amended to add the following statement to their labels, "This plant- incorporated protectant may be combined through conventional breeding with other registered plant- incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other plant- incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits." Both amendments must be approved to register this product. Submit the MON 89034 x MON 88017 label amendment. We anticipate rapid EPA review of these amendments.
- 7) Submit the following data in the time frames listed:

OPPTS Guideline/ Study Type	Required Data	Due Date
Insect Resistance Management	To address the uncertainty regarding CRW dose and buttress the dose assumptions used in the models, provide additional dose data (using the methods of Storer et al. 2006) with Cry3Bb1 and Cry34/35. Further dose studies could also be conducted with varying egg infestation levels (above and below egg levels expected to trigger density-dependent mortality) to tease out any egg density effects. New techniques to assess CRW dose may need to be pursued as well, if Monsanto/Dow or academic researchers can develop such approaches.	Annually Report Due 11/31/2010
Insect Resistance Management	Monsanto/Dow conducted modeling simulations to investigate the effect of initial resistance allele frequency (RAF). The results from these simulations with a pyramid showed that the initial RAF was insensitive in the model -- the final RAF did not increase significantly from the initial frequency after 10 generations of selection (regardless of the starting value). Nevertheless, BPPD is still concerned that resistance alleles for CRW-targeted Bt traits may be relatively common in the field based on published CRW selection studies (Lefko et al. 2008; Meihls et al. 2008). Monsanto/Dow's modeling has assumed an initial RAF of 0.001. This may be suitable for other pests (e.g. lepidoptera), but BPPD must consider the possibility that actual RAF for CRW is higher (perhaps close to 0.01). To	Annually First Report Due 11/31/2010

OPPTS Guideline/ Study Type	Required Data	Due Date
	further investigate this issue, resistance selection experiments must be conducted to further characterize putative resistance alleles and frequency of occurrence in CRW populations.	
Insect Resistance Management	New model simulations must be conducted to incorporate new data (i.e. from studies conducted under items above) or using possible "worst case" parameters. Although Monsanto/Dow's new model simulations have been more conservative than previous runs, BPPD remains concerned that "worst case" scenarios for SmartStax have not yet been fully investigated. CRW-protected corn is highly adopted in some areas with heavy infestations so that intense selection pressure for resistance can be expected. In light of this, and the large proposed reduction in refuge (from 20% to 5%; a 75% total reduction), BPPD believes that worst case analyses are warranted to help determine the potential for resistance. In particular, model parameters for dose and initial resistance allele frequency could be adjusted to include more conservative estimates (e.g. dose ranges < 94% and RAF > 0.001).	Annually First Report Due 11/31/2010

8) Submit or cite all data required to support the Herculex Xtra and the MON 89034 x MON 88017 stacked plant-incorporated protectant products within the timeframes required by the terms and conditions of EPA Registration Numbers 68467-6 and 524-576.

9) You must commit to do the following Insect Resistance Management Program for MON 89034 x TC1507 x MON 88017 x DAS-59122-7.

The required IRM program for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn must have the following elements:

Requirements relating to creation of a non-*Bt* corn refuge in conjunction with the planting of any acreage of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn;

Requirements for Monsanto to prepare and require MON 89034 x TC1507 x MON 88017 x DAS-59122-7 corn users to sign "grower agreements," which impose binding contractual obligations on the grower to comply with the refuge requirements;

Requirements regarding programs to educate growers about IRM requirements;

Requirements regarding programs to evaluate and promote growers' compliance with IRM requirements;

Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1A.105, Cry2Ab2, Cry3A,

Cry1F and Cry34Ab1/Cry35Ab1 proteins in the target insects;
Requirements regarding a "remedial action plan," which contains measures Monsanto/Dow would take in the event that any field-relevant insect resistance was detected as well as to report on activity under the plan to EPA;

Annual reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreements results, and the compliance assurance program including the educational program on or before January 31st each year, beginning in 2011.

a) Refuge Requirements for MON 89034 x TC1507 x MON 88017 x DAS-59122-7

These refuge requirements do not apply to seed propagation of inbred and hybrid corn seed up to a total of 20,000 acres per county and up to a combined U.S. total of 250,000 acres per PIP active ingredient per registrant per year. Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the following refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

A common refuge must be planted for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. Refuge options are based on the planting of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 in cotton or non-cotton growing regions and the insect pressure present in those locations. The refuge sizes for these regions are either 5% in cotton growing regions (i.e. 5 acres of non-Bt corn for every 95 acres MON 89034 x TC1507 x MON 88017 x DAS-59122-7 planted) or 20% in non-cotton growing regions (20 acres of non-Bt corn for every 80 acres of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 planted). If corn rootworms are significant within a region, the structured refuge must be planted as an in-field or adjacent refuge using corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. It can be planted as a block within or adjacent (e.g., across the road) to the MON 89034 x TC1507 x MON 88017 x DAS-59122-7, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). If corn rootworms are not significant within a region, the structured refuge may be planted as an in-field or adjacent refuge or as a separate block that is within 1/2 mile of the MON 89034 x TC1507 x MON 88017 x DAS-59122-7 field. The structured refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

Region	Refuge size	In- field or adjacent refuge	Refuge separated by up to 1/2 mile
Cotton growing where CEW is a significant pest and WCRW, NCRW and MCRW are not significant: NC, SC, GA, FL, TN (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton) AL, MS, LA, VA (only the counties of Dinwiddie, Franklin City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex)	20% non-Bt corn	Yes	Yes
Cotton growing where CEW is a significant pest and WCRW, NCRW, and/or MCRW are significant: AR, TX (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), OK (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), MO (only the counties of Dunkin, New Madrid, Pemiscot, Scott, and Stoddard).	20% non-Bt corn	Yes	No
Cotton growing where CEW is not a significant pest and WCRW, NCRW and MCRW are not significant: NM, AZ, CA, NV Non-cotton growing where WCRW, NCRW and MCRW are not significant OR, WA, ID, MT, WY, UT, VA (except the counties of Dinwiddie, Franklin City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), WV, PA, MD, DE, CT, & NJ, NY, ME, MA, NH, VT, HI, TN (except the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton)	5% non-Bt corn	Yes	Yes
Non-cotton growing where WCRW, NCRW and/or MCRW are significant: KS, NE, SO, NO, MN, IA, MO (except the counties of Dunkin, New Madrid, Pemiscot, Scott, and Stoddard), IL, WI, MI, IN, OH, KY, CO, OK (except the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), TX (only the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman)	5% non-Bt corn	Yes	No

b) Grower Agreement for MON 89034 x TC1507 x MON 88017 x DAS-59122-7Corn

- 1) Persons purchasing *MON 89034 x TC1507 x MON 88017 x DAS-59122-7* corn must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- 2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3) Monsanto must implement a system (equivalent to what is already approved for previously registered Monsanto *Bt* corn products), which is reasonably likely to assure that persons purchasing *MON 89034 x TC1507 x MON 88017 x DAS-59122-7* corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program. A description of the system must be submitted to EPA within 90 days from the date of registration.
- 4) Monsanto must use an approved grower agreement and must submit to EPA, within 90 days from the date of registration, a copy of that agreement and any specific stewardship documents referenced in the grower agreement. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, Monsanto must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this registration.
- 5) Monsanto must implement an approved system (equivalent to what is already approved for previously registered Monsanto *Bt* corn products), which is reasonably likely to assure that persons purchasing *MON 89034 x TC1507 x MON 88017 x DAS-59122-7* corn sign grower agreement(s). A description of the system must be submitted to EPA within 90 days from the date of registration.
- 6) Monsanto shall maintain records of all *MON 89034 x TC1507 x MON 88017 x DAS-59122-7* corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
- 7) Beginning on January 31, 2011 and annually thereafter, Monsanto shall provide EPA with a report on the number of units of *MON 89034 x TC1507 x MON 88017 x DAS-59122-7* corn seed shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of a twelve-month period. Note: The first report shall contain the specified information from the time frame starting with the date of registration and extending through the 2010 growing season.
- 8) Monsanto must allow a review of the grower agreements and grower agreement records by

EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c) IRM Education and IRM Compliance Monitoring Program for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Corn

1) Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to *MON 89034 x TC1507 x MON 88017 x DAS-59122-7* corn users the importance of complying with the IRM program. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by internet, radio, or television commercials. Copies of the materials will be provided to EPA for their records. The program shall involve at least one written communication annually to each *MON 89034 x TC1507 x MON 88017 x DAS-59122-7* corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education program with the educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.

2) Annually, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3) Beginning January 31, 2011, Monsanto must provide a report to EPA summarizing the activities it carried out under its education program for the prior year. Annually thereafter, Monsanto must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Monsanto must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC).

4) Given that *MON 89034 x TC1507 x MON 88017 x DAS-59122-7* will likely have different refuge strategies for lepidoptera and CRW than other registered Bt corn products, you must submit a revised compliance assurance program (CAP) within 90 days of the date of registration. This revised CAP must be found acceptable by BPPD by April 1, 2010. This strategy should be specific for *MON 89034 x TC1507 x MON 88017 x DAS-59122-7* and the new refuge requirements. Availability of non-Bt corn refuge seeds in desirable varieties must be addressed. Compliance is an area of ongoing concern -- recent data have shown that refuge compliance for Bt corn has fallen in recent years.

d) Insect Resistance Monitoring and Remedial Action Plans for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Corn

Existing programs for resistance monitoring and remedial action that were established for MON

89034 (Cry1A.105 and Cry2Ab2), MON 88017 (Cry3Bb1), and Herculex Xtra (Cry1F and Cry34/35) should be applicable to *MON 89034 x TC1507 x MON 88017 x DAS-59122-7* corn. In light of potentially lower overall structured Bt corn structured refuge, the CRW resistance monitoring program must be expanded (i.e. with additional sampling and collection sites or improved monitoring techniques). Also, a revised definition of "resistance" may be needed for the CRW monitoring and remedial action plans based on recent research and selection experiments (Lefko et al. 2008; Meihls et al. 2008). You must submit a revised resistance monitoring and remedial action plan within 90 days of the date of registration that must be found acceptable to BPPD by April 1, 2010.

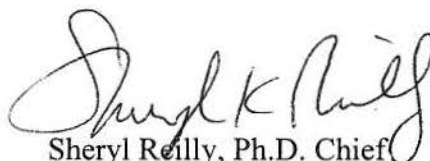
A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year, beginning in 2011, for the duration of the conditional registration.

e) Annual Reporting Requirements for *MON 89034 x TC1507 x MON 88017 x DAS-59122-7* Corn

- 1) Annual Sales: reported and summed by state (county level data available by request) January 31st each year, beginning in 2011;
- 2) Grower Agreements: number of units of *MON 89034 x TC1507 x MON 88017 x DAS-59122-7* corn seed shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year, beginning in 2010;
- 3) Grower Education: substantive changes to education program completed previous year, January 31st each year, beginning in 2011;
- 4) Compliance Assurance Program: compliance assurance program activities and results for the prior year and plans for the compliance assurance program for the current year, January 31st each year, beginning in 2011;
- 5) Compliance Survey Results: results of annual surveys for the prior year and survey plans for the current year; full report January 31st each year, beginning in 2011;
- 6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year, beginning in 2011.

This letter does not mean that EPA agrees to amend the subject product. If Monsanto submits the information in writing as described in this letter, however, EPA will be able to continue to process the registration application.

Sincerely,

A handwritten signature in cursive script, appearing to read "Sheryl K. Reilly".

Sheryl Reilly, Ph.D. Chief
Microbial Pesticide Branch
Biopesticides and Pollution
Prevention Division (7511P)

Support

SCHNEIDER, RUSSELL P [AG/1920]

to:

Alan Reynolds

06/15/2009 04:02 PM

Show Details

Alan,

In April when we first met about the deficiency letter you indicated that support from the academic community would be valuable to you in knowing not only that our request was solid, but also that we and EPA had support for a decision on the 50/o refuge.

If you continue to believe acadmic support is valuable, please respond affirmatively and we will forward your comment to the scientists directly knowledgable of the work.

Thank you,

Russ

Sent from my BlackBerry Wireless Handheld

This e-mail message may contain privileged and/or confidential information, and is intended to be received only by persons entitled to receive such information. If you have received this e-mail in error, please notify the sender immediately. Please delete it and all attachments from any servers, hard drives or any other media. Other use of this e-mail by you is strictly prohibited.

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RE: Dose questions for CRW
Hibbard, Bruce to: Alan Reynolds

04/28/2009 01:26 PM

History: This message has been replied to and forwarded.

Alan, I appreciate being asked my opinion in the matters below.
Attached are my responses with your text below in italics. If I can be
of any further help, please let me know.
Bruce

Bruce E. Hibbard
USDA-ARS
205 Curtis Hall
University of Missouri
Columbia MO 65211-7020

Ph. 573-882-6281
FAX 573-882-3801
Email Bruce.Hibbard@ars.usda.gov

-----Original Message-----

From: Reynolds.Alan@epamail.epa.gov
[mailto:Reynolds.Alan@epamail.epa.gov]
Sent: Monday, April 27, 2009 3:19 PM
To: Hibbard, Bruce
Cc: Martinez.Jeannette@epamail.epa.gov
Subject: Dose questions for CRW

Hi Bruce-

I hope you are doing well this spring and are gearing up for this
summer's field season.

As you are probably aware, EPA/BPPD is considering two proposals from
biotech companies to modify the existing structured refuge requirements
for CRW (currently a 20% non-Bt corn refuge). As we review these
proposals, the issue of "dose" for CRW has emerged as a key topic,
particularly as it relates to assumptions being used in simulation
models to support lower CRW refuges. I was wondering if I could tap
your expertise to help us answer (or better understand) some of the
issues surrounding dose for CRW. While I can't discuss the industry
data in specific detail, I was hoping to ask for advice on a more
general scale.

Dose for CRW has always been a tricky issue for EPA to evaluate, because
the biology of the insect does not fit neatly into the previous
definitions developed for lepidoptera. Instead, the registrants have
cited the methodology described by Storer et al. (2006) to calculate
dose for both the Cry34/35 (Herculex RW) and Cry3Bb1 (Yieldgard RW)
proteins. Storer's technique involves using adult emergence data (from
artificial egg infestations) and correcting for density dependent
mortality in the control groups. EPA has historically considered both
Cry3Bb1 and Cry34/35 to be "less than high dose" (Cry3Bb1: low to
moderate dose; Cry34/35: close to high dose). However, the registrants
have implied that the doses of their toxins (as expressed in their Bt
corn lines) are actually closer to high dose (i.e. resulting in >99%
mortality) when calculated using Storer et al. (2006). Along these
lines, here are some of the questions I am trying to answer....

47

1) In your opinion, is Storer et al. (2006) an appropriate (or realistic) method to calculate dose for CRW? Has the methodology described in the paper been widely accepted by CRW researchers?

2) Storer's paper assumes that "(density dependent) mortality is not a factor (for Cry34/35) because the trait drastically reduces the density of larvae." Is this a reasonable assumption or is it possible that larvae exposed to a Cry34/35 stand could still undergo some density dependent mortality? Could density independent mortality (i.e. mortality before exposure to the Cry34/35 toxin) confound this assumption?

3) Storer's paper concluded that the estimated dose mortality of Cry34/35 using his methodology was 99.14 to 99.98%. Do you think this is realistic?

4) Likewise, Storer's methods have also been recently applied (unpublished data) to Cry3Bb1 with similar conclusions (dose mortality > 99%). Based on your experience, is this a reasonable conclusion for Cry3Bb1?

5) The recent paper published from your laboratory (Miehls et al. 2008) demonstrated that resistance to Cry3Bb1 can be selected quickly in the greenhouse (3 generations). Does this work have any implications for estimates of Cry3Bb1 dose mortality?

6) There have also been suggestions that CRW toxins may have some "non-lethal" activity including repellency. Could this impact the issue of dose for CRW-protected corn varieties?

I apologize for being long-winded, but given the importance of the decisions EPA/BPPD has to make this summer for the future of CRW IRM, I want to be as well informed as possible. Any help you can provide to help us better understand the issues will be greatly appreciated. Please feel free to call or e-mail if you would like to discuss this further.

Thanks for your help!!!

Best regards,
Alan Reynolds, EPA
(703) 605--0515



EPA correspondence 2009.doc

Hi Bruce-

I hope you are doing well this spring and are gearing up for this summer's field season.

As you are probably aware, EPA/BPPD is considering two proposals from biotech companies to modify the existing structured refuge requirements for CRW (currently a 20% non-Bt corn refuge). As we review these proposals, the issue of "dose" for CRW has emerged as a key topic, particularly as it relates to assumptions being used in simulation models to support lower CRW refuges. I was wondering if I could tap your expertise to help us answer (or better understand) some of the issues surrounding dose for CRW. While I can't discuss the industry data in specific detail, I was hoping to ask for advice on a more general scale.

Dose for CRW has always been a tricky issue for EPA to evaluate, because the biology of the insect does not fit neatly into the previous definitions developed for lepidoptera. Instead, the registrants have cited the methodology described by Storer et al. (2006) to calculate dose for both the Cry34/35 (Herculex RW) and Cry3Bb1 (Yieldgard RW) proteins. Storer's technique involves using adult emergence data (from artificial egg infestations) and correcting for density dependent mortality in the control groups. EPA has historically considered both Cry3Bb1 and Cry34/35 to be "less than high dose" (Cry3Bb1: low to moderate dose; Cry34/35: close to high dose). However, the registrants have implied that the doses of their toxins (as expressed in their Bt corn lines) are actually closer to high dose (i.e. resulting in >99% mortality) when calculated using Storer et al. (2006). Along these lines, here are some of the questions I am trying to answer....

1) In your opinion, is Storer et al. (2006) an appropriate (or realistic) method to calculate dose for CRW? Has the methodology described in the paper been widely accepted by CRW researchers?

The tent technique is the only realistic method to calculate dose for the western corn rootworm that I am aware of. For calculation of dose, the technique requires knowledge of eggs going in (artificial infestation) and adults coming out from both isoline and Bt. For an accurate calculation, it is also critical to understand density-dependent mortality. I will address this last point further under question 3.

In general, I believe that the tent technique has been widely adapted and accepted. The screen tent technique was developed and used by Tom Clark (formerly a postdoc in my lab, then an assistant professor at the University of Missouri, and now with Monsanto) and I in 2003 for evaluating selection intensity of Cry3Bb1. This was the same year that Storer first used it, so I believe we developed very similar techniques independently. Overall we have used the technique extensively every year since 2003 and it has been used by Pioneer, Syngenta, Monsanto and Dow for internal use. I am also aware of its use in Nebraska (Lance Meinke), Iowa (Dan Moellenbeck and Aaron Gassmann), South Dakota (Wade French) Minnesota (Ken Ostlie), Indiana (Christian Krupke), Illinois (Mike Gray and Kevin Steffey), and Missouri (Wayne Bailey).

2) Storer's paper assumes that "(density dependent) mortality is not a factor (for Cry34/35) because the trait drastically reduces the density of larvae." Is this a reasonable assumption or is

it possible that larvae exposed to a Cry34/35 stand could still undergo some density dependent mortality? Could density independent mortality (i.e. mortality before exposure to the Cry34/35 toxin) confound this assumption?

I believe that this is a reasonable assumption. In his model, Storer (2003) included an assumption that “most density-dependence occurs after the larvae have become established but before they have reached adulthood.” Hibbard et al. (2004) evaluated 100, 200, 400, 800, 1600, and 3200 eggs per infested plant and documented that a similar percentage of larvae established on a plant regardless of infestation rate, supporting Storer’s (2003) assumption that density-dependent mortality is negligible during establishment. A definition of density-dependent mortality for corn rootworm larvae is mortality of 2nd and especially 3rd instar larvae resulting from a lack of available suitable host material for later developing larvae. Density independent mortality factors are high (causing 90 to 95% mortality prior to establishment), but these should be independent of dose.

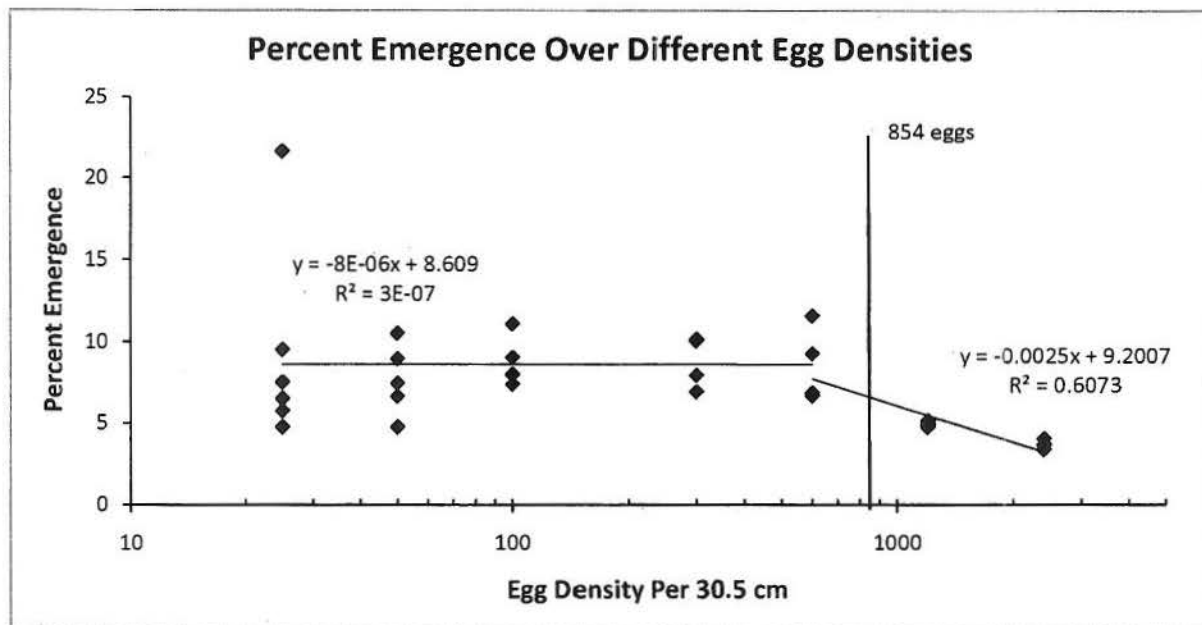
3) Storer's paper concluded that the estimated dose mortality of Cry34/35 using his methodology was 99.14 to 99.98%. Do you think this is realistic?

The short answer to this question is that I believe what the raw data indicate (a much lower figure). Raw data from Storer et al. (2006) are as follows:

Environment	Year	# WCR Isoline	# WCR Cry34/35	% Rel. Survival	Cry34/35 Selection intensity
Fowler, IN	2003	534.2	3.2	0.60	99.40
Slater, IA	2003	1069	35.2	3.29	96.71
Fowler, IN	2004	402.3	27	6.71	93.29
Average		668.5	21.80	3.53	96.47

Storer et al. (2006) infested with 3300 eggs per meter at one location and 3600 eggs per meter at another. Egg hatch timing and proportion data were collected, but this was not reported. Assuming approximately 75% viable eggs, actual infestation of viable eggs were 2,475 or 2,700 viable eggs per meter. This translates to 754 or 822 eggs per 30.5 cm (foot).

My group evaluated egg densities of 25, 50, 100, 300, 600, 1200, and 2400 VIABLE eggs per 30.5 cm in tent studies on “normal” corn in 2005 and 2007. The percentage of adults emerging did not change from 25 eggs per 30.5 cm to 600 eggs per 30.5 cm (see figure below). When PROC NLIN was used to fit a straight line – single breakpoint regression, the breakpoint estimate was 854. It is my contention that this breakpoint is the egg density where density-dependent mortality began in that location that year. We are just writing this experiment up now and have also began this analysis for the 2007 data. Regardless of where the exact breakpoint might have been in the three locations evaluated in Storer et al. (2006), given our data, it is likely that little, if any, density-dependent mortality occurred.



For the Syngenta selection intensity experiments led by our group, we evaluated three egg densities (1500, 3000, and 6000 viable eggs per meter) and could document whether or not density-dependent mortality in the control occurred by evaluating the percentage emergence in the controls at different egg densities.

4) Likewise, Storer's methods have also been recently applied (unpublished data) to Cry3Bb1 with similar conclusions (dose mortality > 99%). Based on your experience, is this a reasonable conclusion for Cry3Bb1?

In a randomized complete block experiment, of MON863, MON88017, and Cry34/35Ab1, both Cry34/35Ab1 and MON88017 provided slightly better control than MON863. Selection intensity of MON88017 and Cry34/35Ab1 were not significantly different. My answer to question 3 would apply for Cry3Bb1.

5) The recent paper published from your laboratory (Meihls et al. 2008) demonstrated that resistance to Cry3Bb1 can be selected quickly in the greenhouse (3 generations). Does this work have any implications for estimates of Cry3Bb1 dose mortality?

I would argue that resistance alleles to Cry3Bb1, mCry3A, and Cry34/35Ab1 are relatively common given our published and unpublished data and the data of Lefko et al. (2008). Whether or not these resistance alleles lead to full survival relative to isoline survival (full resistance in the traditional sense) is a different question. Whether or not our data have implications on dose is a question probably better answered by Aaron Gassmann, Bruce Tabashnik, or others with more expertise in population genetics.

6) There have also been suggestions that CRW toxins may have some "non-lethal" activity including repellency. Could this impact the issue of dose for CRW-protected corn varieties?

The short answer to this question, in my opinion, is yes. At present, this is the question with the least amount of data associated with it, though. This is something that we are actively thinking about and beginning to work on. We have no data ready to send you at this time. One could speculate that feeding behavior is a component of the resistance that we and Lefko et al. (2008) have found. If so, would a feeding behavior component have more cross resistance than a physiological resistance? I would speculate that the answer is yes. However, there is only minimal data to support these speculations. We have not been allowed seed access by Monsanto or DowAgrosciences to do the logical cross resistance studies that I would say would be relevant to a stack of these events.

I apologize for being long-winded, but given the importance of the decisions EPA/BPPD has to make this summer for the future of CRW IRM, I want to be as well informed as possible. Any help you can provide to help us better understand the issues will be greatly appreciated. Please feel free to call or e-mail if you would like to discuss this further.

Thanks for your help!!!

*Best regards,
Alan Reynolds, EPA
(703) 605--0515*

References Cited

Hibbard, B.E., M.L. Higdon, D.P. Duran, Y.M. Schweikert, and M.R. Ellersieck. 2004. Role of egg density on establishment and plant-to-plant movement by western corn rootworm larvae (Coleoptera: Chrysomelidae). J. Econ. Entomol. 97: 871-882.

Lefko, S.A, T.M. Nowatzki, S.D. Thompson, R.R. Binning, M.A. Pascual, M.L. Peters, and B.H. Stanley. 2008. Characterizing laboratory colonies of western corn rootworm (Coleoptera: Chrysomelidae) selected for survival on maize containing event DAS-59122-7. J. Appl. Entomol. 132:189-204.

Meihls, L.N., M.L. Higdon, B.D. Siegfried, T.A. Spencer, N.J. Miller, T.W. Sappington, M.R. Ellersieck, and B.E. Hibbard. 2008. Increased survival of western corn rootworm on transgenic corn within three generations of on-plant greenhouse selection. Proceedings of the National Academy of Science 105: 19177-19182.

Storer, N. P. 2003. A spatially explicit model simulating western corn rootworm (Coleoptera: Chrysomelidae) adaptation to insect-resistant maize. J. Econ. Entomol. 96: 1530-1547.

Storer, N. P., J. M. Babcock, and J. M. Edwards. 2006. Field measures of western corn rootworm (Coleoptera: Chrysomelidae) mortality caused by Cry34/35Ab1 proteins

SmartStax corn

Richard Roush

to:

Alan Reynolds, Janet Andersen, Debbie Edwards

06/18/2009 09:32 AM

Show Details

History: This message has been replied to.

June 18, 2009

To: Dr. Alan Reynolds, Entomologist

Dr. Janet Andersen, Director, Biopesticide and Pollution Prevention Division

Dr. Debbie Edwards, Director, Office of Pesticide Programs

From: Rick Roush, Dean

Melbourne School of Land and Environment

University of Melbourne, Vic 3010

RE: SmartStax corn

For more than a decade, as highlighted in the papers at the end of this memo, my colleagues (especially Professor Tony Shelton) and I have investigated various tactics for management of resistance to Bt transgenic insecticidal crops. A key conclusion is that we should encourage the development and deployment of crop varieties that include at least two effective Bt genes (pyramided toxins), which will increase durability of Bt crops, even with the smaller refuge sizes that growers desire for resistance management to be more economically practical.

As you would know, I don't support every proposal for pyramided Bt crops (e.g., I couldn't be convinced by a recent proposal from Pioneer for its AcreMax). To be effective in resistance management, pyramided Bt crops need a minimal

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combination of refuge size and good expression of the genes (Roush 1998).

I have had the opportunity over the last year to review in some detail the development of SmartStax corn, with its multiple effective Bt proteins for both lepidoptera and corn rootworms. I write to encourage the registration, deployment, and grower adoption of SmartStax with refuges of at least 5% refuge in the northern Corn Belt and 20% in southern cotton-growing areas. I am convinced that this will be a significant improvement in resistance management over current Bt corn varieties.

Please feel free to contact me if you would like additional information on my views.

References

Roush, R. T. 1998. Two toxin strategies for management of insecticidal transgenic crops: Can pyramiding succeed where pesticide mixtures have not? *Philosophical Transactions of the Royal Society of London, Series B, Biological Sciences* 353: 1777-1786

Zhao, J. Z., J. Cao, Y. Li, H. L. Collins, R. T. Roush, E. D. Earle, and A. M. Shelton. 2003. Transgenic plants expressing two *Bacillus thuringiensis* toxins delay insect resistance evolution. *Nature Biotechnology* 21: 1493-97.

Zhao, J.-Z., J. Cao, H. L. Collins, S. L. Bates, R. T. Roush, E. D. Earle, and A. M. Shelton. 2005. Concurrent use of transgenic plants expressing a single and two *Bacillus thuringiensis* genes speeds insect adaptation to pyramided plants. *Proc. Natl. Acad. Sci.* 102: 8426-8430.

54



SmartStax

Tony Shelton to: Alan Reynolds, Janet Andersen, Debbie Edwards

06/16/2009 10:14 PM

Attached and listed below are my comments regarding the SmartStax corn product you are currently reviewing. I am also attaching our Nature Biotechnology (2003) paper that is very relevant to this issue.

Sincerely,
Tony Shelton, Ph.D.
June 16, 2009

Dr. Alan Reynolds, Entomologist
Dr. Janet Andersen, Director, Biopesticide and Pollution Prevention Division
Dr. Debbie Edwards, Director, Office of Pesticide Programs

As an entomologist in the public sector who works on insecticide resistance management (IRM) on transgenic insecticidal plants, I wish to offer my thoughts on the SmartStax corn product that you are currently reviewing. With various IRM proposals in front of EPA, and limited opportunities for public comment, I wanted to ensure that EPA was aware of how someone from the public sector whose work has focused on IRM views the relevant issues.

For more than a decade, one of the foci of my research has been the potential value of transgenic pyramided products for IRM and how such plants can fit into overall integrated pest management (IPM) programs. That work, and work of my colleagues including Dr. Rick Roush, has demonstrated that pyramids of two individually effective Bt proteins with distinct modes of action can dramatically delay resistance compared to single-protein products. This research was funded by USDA competitive grants and one article in particular we published in Nature Biotechnology in 2003 (see attached) is very relevant to your review. That article contains the following sentence based on the conclusions from our study: "We believe industry should be encouraged to develop such plants (pyramided toxins) for their increased durability for insect management and we suggest that the smaller refuge size required by pyramided toxins plants may be an additional incentive for them to do so".

From a technical perspective, the most effective strategy to reduce the risk of resistance evolution to Bt crops is to encourage a transition from the current single-protein products to pyramided products. That transition has successfully occurred in cotton with the move from Bollgard cotton to Bollgard II and WideStrike cotton and this was encouraged by EPA's decision to grant the pyramided products a natural refuge option.

SmartStax corn, with multiple effective Bt proteins for both lepidopteran and rootworm control, offers a similar opportunity in corn and its use should be promoted by EPA so that the full environmental benefits of this reduced-risk technology can be achieved. Such a product will still

provide an excellent IRM strategy even with a significantly smaller refuge than is required for current Bt corn products, and granting a smaller refuge for SmartStax corn and comparable pyramided corn products will encourage growers to move to these lower risk products. I note that EPA has already granted MON 89034 corn - a component of SmartStax - a 5% refuge in the corn belt and I encourage EPA to make a similar decision for the SmartStax corn product. If you have any questions about my statements or want additional information, please contact me. Thank you for your consideration of my input.

Sincerely,
Tony Shelton
Professor of Entomology
Professor and Associate Director of International Agriculture

--

Tony Shelton: ams5@cornell.edu
Professor, Department of Entomology
International Professor; Associate Director International Programs
Cornell University/NYSAES, 630 W. North St., Geneva NY 14456
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Zhao 03NB 2 gene.pdf EPA letter on SmartStax.doc



April 23, 2009

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RESUBMISSION
M.M.

Attn: Dr. Janet Andersen;

Director, Biopesticide and Pollution Prevention Division (7511P)

Subject: Supplemental Information - Benefits

Product Name: MON 89034 × TC1507 × MON 88017 × DAS-59122-7

EPA File Symbol: 524-LIR (MON); 68467-T (DAS)

OPP Decision Numbers: D-394799 (MON); D-395123 (DAS)

EPA Application Receipt Dates: June 12 and June 13, 2008

Dear Dr. Andersen,

Monsanto Company and Mycogen Seeds c/o Dow AgroSciences LLC (DAS) submitted applications for the registration of the combined plant-incorporated protectants, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStax™) on June 12 and June 13, respectively.

Monsanto, on behalf of Monsanto and DAS, provided information on the benefits of SmartStax with a 5% refuge, in support of both registrations on April 10, 2009. In the current submission, Monsanto, on behalf of Monsanto and DAS, is providing additional supporting information on farm-level benefits of SmartStax, in support of both registrations. Since the attached information has not been published at this time, the authors have requested that it remain confidential and has been designated accordingly.

This letter includes one attachment that is classified as confidential category "C"

Document	Category
Farm-Level Benefits of a Refuge Reduction for SmartStax™ Corn Hybrids	C

57

Jan

Regulatory Affairs Manager, Monsanto Company

cc: Dr. Sheryl Reilly, EPA BPPD
Dr. Chris Wozniak, EPA BPPD
Mr. Mike Mendelsohn, EPA BPPD
Dr. Russell Schneider, Monsanto Company
Dr. Penny Hunst, Dow AgroSciences

58

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Pages 59 through 65 are not included in this copy.

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April 10, 2009

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<http://www.monsanto.com>

Attn: Dr. Janet Andersen;

Director, Biopesticide and Pollution Prevention Division (7511P)

Subject: Supplemental Information - Benefits
Product Name: MON 89034 × TC1507 × MON 88017 × DAS-59122-7
EPA File Symbol: 524-LIR (MON); 68467-T (DAS)
OPP Decision Numbers: D-394799 (MON); D-395123 (DAS)
EPA Application Receipt Dates: June 12 and June 13, 2008

Dear Dr. Andersen,

Monsanto Company and Mycogen Seeds c/o Dow AgroSciences LLC (DAS) submitted applications for the registration of the combined plant-incorporated protectants, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStaxTM) on June 12 and June 13, respectively.

Monsanto, on behalf of Monsanto and DAS, is providing additional information on the benefits of SmartStax with a 5% refuge, in support of both registrations. This information is contained within the confidential attachment to this letter.

This letter includes one attachment that is classified as confidential category "C"

Document	Category
The Benefits of Refuge Reduction to 5% for SmartStax Corn	C

66

If you have any questions regarding this response letter, please do not hesitate to contact Dr. Russell Schneider at 202-383-2866 or myself at 314-694-6514.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Austin Burns", followed by the text "(for)".

J. Austin Burns, Ph.D.

Regulatory Affairs Manager, Monsanto Company

cc: Dr. Sheryl Reilly, EPA BPPD
Dr. Chris Wozniak, EPA BPPD
Mr. Mike Mendelsohn, EPA BPPD
Dr. Russell Schneider, Monsanto Company
Dr. Penny Hunst, Dow AgroSciences

5

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Pages 69 through 77 are not included in this copy.

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April 9, 2009

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Attn: Dr. Sheryl Reilly

Subject: EPA Data Deficiency Letters, Dated March 19, 2009
Product Name: MON 89034 × TC1507 × MON 88017 × DAS-59122-7
EPA File Symbol: 524-LIR (MON); 68467-T (DAS)
OPP Decision Numbers: D-394799 (MON); D-395123 (DAS)
EPA Application Receipt Dates: June 12 and June 13, 2008

Dear Dr. Reilly,

Monsanto Company and Mycogen Seeds c/o Dow AgroSciences LLC (DAS) submitted applications for the registration of the combined plant-incorporated protectants, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 on June 12 and June 13, respectively. On June 16, the applications were assigned PRIA category B880, and the BPPD assigned a decision date of March 30, 2009.

On March 20, 2009, Monsanto and DAS each received a letter from the EPA BPPD dated March 19, 2009 citing deficiencies in our applications to register MON 89034 × TC1507 × MON 88017 × DAS-59122-7. The March 19 letters noted that a prompt response and renegotiation of the PRIA decision date was necessary in order for BPPD to have sufficient time to complete their review of the requested information and to make a registration decision. In order to accomodate this request, both companies met with the Agency on March 26, 2009, and also requested a thirty-day extension to the March 30 PRIA decision date to allow further negotiation. Because the cited deficiencies were minor and could be addressed by supplying additional model calculations and clarifications only, Monsanto, on behalf of both Monsanto and DAS, is providing the additional information necessary to complete the review supporting both registrations with a 5% structured refuge. The information addressing each question is contained within the confidential attachment to this letter.

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Commercialization of SmartStax (MON 89034 × TC1507 × MON 88017 × DAS-59122-7) with a 5% refuge will provide unparalleled insect pest protection, greater economic returns and important environmental benefits to U.S. corn growers and society.

SmartStax corn will provide superior protection from both above and below ground insect pests and pyramided Bt proteins for greater durability for managing target pests. Importantly, SmartStax corn technology provides the opportunity to reduce structured refuge to 5% of the grower's acres, benefits that are not provided by other Bt corn products currently available in the marketplace. The insecticidal proteins in SmartStax corn are highly efficacious against the corn rootworm complex (*Diabrotica* spp.) as well as all of the major, and many of the minor, lepidopteran pests of corn in the U.S. The product provides overall above and below ground insect protection that is superior to the current single Bt-protein corn products in the marketplace, with substantially greater durability for both orders of pests. SmartStax corn has value for the entire U.S. field corn production market.

SmartStax corn with a 5% refuge will provide greater economic returns and important environmental benefits to U.S. corn growers and society. Growers planting SmartStax corn with a 5% refuge will realize significant economic value from increased yield, reduced insecticide cost, discounted crop insurance premiums and other non-pecuniary benefits. SmartStax corn with a 5% refuge will provide increased flexibility for planting refuges and make planting refuges easier and more convenient. Planting SmartStax corn on 95% versus 80% of corn acres will eliminate the use of from 0.43 to 1.0 M lbs ai of soil-applied insecticides in the insecticide-treated refuge and reduce the potential for insecticide residues in the environment. Planting SmartStax corn on 15% more acres with a 5% refuge option also will provide more protection from ear feeding insects and help to increase grain quality and avoid market losses. As the global demand for corn continues to expand, the increased yield per acre produced using this technology will help to meet the world's needs for food, feed and fuel more sustainably.

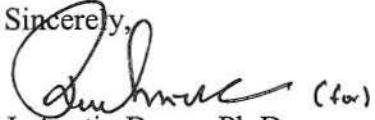
Detailed benefits information regarding these points will be provided in a document under a separate cover letter.

This letter includes one attachment classified as confidential category "C"

Document	Category
Response to EPA Letter of March 19, 2009	C

If you have any questions regarding this response letter, please do not hesitate to contact Dr. Russell Schneider at 202-383-2866 or myself at 314-694-6514.

Sincerely,

A handwritten signature in dark ink, appearing to read "J. Austin Burns", followed by the text "(for)".

J. Austin Burns, Ph.D.

Regulatory Affairs Manager, Monsanto Company

cc: Mr. Mike Mendelsohn, EPA BPPD
Mr. Alan Reynolds, EPA BPPD
Dr. Russell Schneider, Monsanto Company
Dr. Penny Hunst, Dow AgroSciences

CONFIDENTIAL ATTACHMENT

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* The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

New PRIA date

SCHNEIDER, RUSSELL P [AG/1920]

to:

Janet Andersen

04/23/2009 01:12 PM

Cc:

Mike Mendelsohn

Show Details

History: This message has been replied to and forwarded.

Dr. Andersen,

Per our discussion with you on April 22, 2009, Monsanto agrees to extend the PRIA date for SmartStax, EPA Reg. No. 524-LIR, OPP Decision Number D-394799, from the recently negotiated April 30, 2009 date until July 31, 2009.


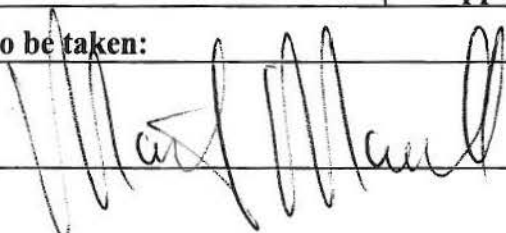
Thank you,

Russ

This e-mail message may contain privileged and/or confidential information, and is intended to be received only by persons entitled to receive such information. If you have received this e-mail in error, please notify the sender immediately. Please delete it and all attachments from any servers, hard drives or any other media. Other use of this e-mail by you is strictly prohibited.

All e-mails and attachments sent and received are subject to monitoring, reading and archival by Monsanto, including its subsidiaries. The recipient of this e-mail is solely responsible for checking for the presence of "Viruses" or other "Malware". Monsanto, along with its subsidiaries, accepts no liability for any damage caused by any such code transmitted by or accompanying this e-mail or any attachment.

**Recommendation of Division Directors
Negotiated Due Dates**

Decision#: 394799	Registration#: 524-LIR	Petition #: N/A
Fee Category: B880	PRIA Decision Time Frame: 9 mos.	
Submitted by: A. Reynolds/ M. Mendelsohn, BPPD	Branch: MPB	Date: 4/23/09
Company: Monsanto Company		
Original Due Date: 3/30/09	Proposed New Due Date: 7/31/09	
Previous Negotiated Due Dates: Yes		
Is the "Fix" in-house? Yes	If not, date "Fix" expected:	
Issue (describe in detail): BPPD has reviewed data submitted by the registrant (Monsanto) in support of SmartStax, a new PIP registration containing five active ingredients. The reviews identified deficiencies in the product characterization and insect resistance management data. These deficiencies must be addressed prior to registration. Monsanto was informed of these deficiencies in a "75-day" letter dated 3/19/09. A 30 day renegotiation was granted on 3/27/09 to allow time for 1) Monsanto to formulate and submit a response, and 2) BPPD to determine the necessary time to review the resubmission. Monsanto submitted their response on April 9, 2009. BPPD asked for 5 ½ months for review, but Monsanto was firm for a 90 day renegotiation. If BPPD determines that the current submission does not adequately support the registration, another renegotiation or a cannot grant decision may be necessary.		
Summary of Deficiency Type(s): Not Submitted (N) <input checked="" type="checkbox"/> Deficiencies (D) Product Chemistry: <input checked="" type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input type="checkbox"/> Other (describe): <input checked="" type="checkbox"/> (insect resistance management)		
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): Monsanto was informed of the original data deficiencies in a 75 day letter dated 3/19/09. BPPD met with the registrant on 3/26/09 to discuss the data and their proposal to address the deficiencies. Monsanto indicated that they would submit a response within one week. An e-mail from Monsanto agreeing to a renegotiated date of 4/30/09 was received by BPPD on 3/26/09. The PRIA date was renegotiated to 4/30/09 on 3/27/09. On 4/22/09, Monsanto agreed to extend the PRIA date to 7/31/09 but not for an extra 5 ½ months as requested by BPPD.		
"75 Day" Letter sent? <input checked="" type="checkbox"/> (sent: 3/19/09) Yes <input type="checkbox"/> No and reason for none?		
Rationale for Proposed Due Date: The 90 day extension of the PRIA due date will allow time for BPPD to review the resubmission and prepare a notice of registration. . However, if BPPD determines that the current submission does not adequately support the registration, another renegotiation or a cannot grant decision may be necessary.		
Registrant notified that this is the last negotiation? Yes <input type="checkbox"/> <input checked="" type="checkbox"/> Not Applicable		
Approve: 	Disapprove:	
If disapproved, action to be taken:		
OD or DOD Signature: 	Date: 4-28-09	

**ROUTING AND TRANSMITTAL SLIP
FOR PRIA RENEGOTIATION**

TO:

INITIALS/DATE

- | | |
|--|---------------------|
| 1. Branch Chief:
Sheryl Reilly | <u>SKR 14/23/09</u> |
| 2. Janet Andersen, Division Director
(place in Renegotiation box) | <u>JZA 14/27/09</u> |
| 3. Doris Mack (Rm.S12624) | <u>DM 14/27</u> |
| 4. Marty Monell, Deputy Office Director | <u>MM 14-26</u> |
| 5. Doris Mack:
(copy to Elizabeth Leovey) | <u>/</u> |
| 6. Janet Andersen (Rm. S8723)
Diana Hudson (Rm. S8953) | <u>/</u> |

Remarks: 2nd Renegotiation for SmartStax (68467-T)

*These are per - one data package for both.
Return to Janet Andersen
or
Sheryl Reilly.*

RECEIVED
IO
APR 27 2009
10291

FROM: Alan Reynolds

Rm. #: S-8937

PHONE #: 703-605-0515

Mail Code: 7511P

(F:/user/share/BPPD/Forms/Routing Slip for Renegotiation)

Checklist for Renegotiation Approval Process

Registration Package

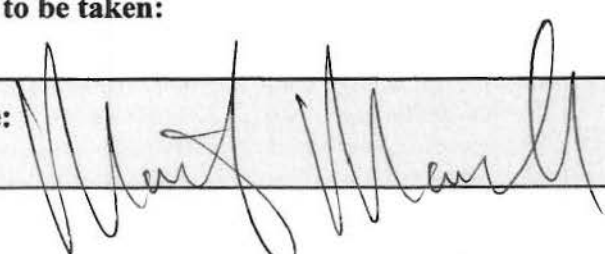
- ☒ 2 copies of current form; Succinctly answer all questions, especially:
 - (1) is fix in?
 - (2) if not, when will fix come in?
 - (3) category of deficiency (i.e., 86-5, product chemistry)
- ☒ 1 copy of e-mail or letter from Registrant/Consultant accepting new proposed date
- ☒ Separate folder and forms for each decision number being renegotiated

Re-negotiation Approval Process

- ☒ Place completed form in renegotiation box in Division Director's office
- ☒ Form to Doris Mack for log-in and routing to Marty Monell
- ☐ Form BPPD box then return form to Janet Andersen or Diana Hudson

BPPD Processing Procedures

- ☐ Make date change in OPPIN and returned package to RAL
- ☐ Inform Todd Peterson by email of due date change and cc: to appropriate Branch Chief
- ☐ Copy to Diana Hudson
- ☐ Original to RAL
- ☐ RAL sends email with new date to applicant
- ☐ RAL electronically updates share/fees by scanning signed renegotiation form or saving file updated with approval date
- ☐ RAL puts original form and copies of all relevant emails in the Jacket

Recommendation of Division Directors Negotiated Due Dates		
Decision#: 394799	Registration#: 524-LIR	Petition #: N/A
Fee Category: B880	PRIA Decision Time Frame: 9 mos.	
Submitted by: A. Reynolds, BPPD	Branch: MPB	Date: 3/27/09
Company: Monsanto Company		
Original Due Date: 3/30/09	Proposed New Due Date: 04/30/09	
Previous Negotiated Due Dates: N/A		
Is the "Fix" in-house? No	If not, date "Fix" expected: 4/1/09	
<p>Issue (describe in detail): BPPD has reviewed data submitted by the registrant (Monsanto) in support of SmartStax, a new PIP registration containing five active ingredients. The reviews identified deficiencies in the product characterization and insect resistance management data. These deficiencies must be addressed prior to registration. Monsanto was informed of these deficiencies in a "75-day" letter dated 3/19/09. Given the short time before the PRIA due date, there is insufficient time for the registrant to submit a response to the deficiencies and for BPPD to review the response. A 30 day renegotiation is proposed to allow time for 1) Monsanto to formulate and submit a response, and 2) BPPD to determine the necessary time to review the resubmission. If BPPD determines that additional time is needed for review, a second PRIA date renegotiation may be necessary.</p>		
<p>Summary of Deficiency Type(s): Not Submitted (N) <input checked="" type="checkbox"/> Deficiencies (D) Product Chemistry: <input checked="" type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input type="checkbox"/> Other (describe): <input checked="" type="checkbox"/> (insect resistance management)</p>		
<p>Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): Monsanto was informed of the data deficiencies in a 75 day letter dated 3/19/09. BPPD met with the registrant on 3/26/09 to discuss the data and their proposal to address the deficiencies. Monsanto indicated that they would submit a response within one week. An e-mail from Monsanto agreeing to a renegotiated date of 4/30/09 was received by BPPD on 3/26/09.</p>		
<p>"75 Day" Letter sent? <input checked="" type="checkbox"/> (sent: 3/19/09) Yes <input type="checkbox"/> No and reason for none?</p>		
<p>Rationale for Proposed Due Date: The 30 day extension of the PRIA due date will allow time for 1) Monsanto to formulate and submit a response, and 2) BPPD to determine the necessary time to review the resubmission. Once received, BPPD will screen the response and determine how much additional time (if any) will be needed to complete a review. If BPPD determines that additional time is needed for review, a second PRIA date renegotiation may be necessary.</p>		
<p>Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable</p>		
Approve: <input checked="" type="checkbox"/>	Disapprove: <input type="checkbox"/>	
If disapproved, action to be taken:		
OD or DOD Signature: 	Date: 3-27-09	

Checklist for Renegotiation Approval Process

Registration Package

- ☒ 2 copies of current form; Succinctly answer all questions, especially:
 - (1) is fix in?
 - (2) if not, when will fix come in?
 - (3) category of deficiency (i.e., 86-5, product chemistry)
- ☒ 1 copy of e-mail or letter from Registrant/Consultant accepting new proposed date
- ☒ Separate folder and forms for each decision number being renegotiated

Re-negotiation Approval Process

- ☒ Place completed form in renegotiation box in Division Director's office
- ☒ Form to Doris Mack for log-in and routing to Marty Monell
- ☐ Form BPPD box then return form to Janet Andersen or Diana Hudson

BPPD Processing Procedures

- ☐ Make date change in OPPIN and returned package to RAL
- ☐ Inform Mary Paden by email of due date change and cc: to appropriate Branch Chief
- ☐ Copy to Diana Hudson
- ☐ Original to RAL
- ☐ RAL sends email with new date to applicant
- ☐ RAL electronically updates share/fees by scanning signed renegotiation form or saving file updated with approval date
- ☐ RAL puts original form and copies of all relevant emails in the Jacket

**ROUTING AND TRANSMITTAL SLIP
FOR PRIA RENEGOTIATION**

Date: 3/27/09

TO:

INITIALS/DATE

- | | |
|--|--|
| 1. Branch Chief:
Sheryl Reilly | <u>SKR</u> <u>3/27/09</u> |
| 2. Janet Andersen, Division Director
(place in Renegotiation box) | <u>JEA</u> <u>3/27/09</u> |
| 3. Doris Mack (Rm.S12624) | <u>DM</u> <u>3/27</u> |
| 4. Marty Monell, Deputy Office Director | <u>MM</u> <u>3-27</u> |
| 5. Doris Mack:
(copy to Elizabeth Leovey) | <u> </u> <u>/</u> <u> </u> |
| 6. Janet Andersen (Rm. S8723)
Diana Hudson (Rm. S8953) | <u> </u> <u>/</u> <u> </u> |

Remarks: Renegotiation for SmartStax (524-LIR)

FROM: Alan Reynolds

Rm. #: S-8937

PHONE #: 703-605-0515

Mail Code: 7511P

RECEIVED

FO

MAR 27 2009

10238

///

MAR 19 2009

OPP Decision Numbers:D-394799

Dr. J. Austin Burns
Regulatory Affairs Manager
Monsanto Company
800 North Lindbergh Blvd
St. Louis, MO 63167

Dear Dr. Burns:

Subject: Data Deficiency

Product Name: MON 89034 x TC1507 x MON 88017 x DAS-59122-7

EPA File Symbols: 524-LIR

Application Date: June 11, 2008

EPA Receipt Date: June 12, 2008

Your application as submitted for registration in accordance with FIFRA Section 3(c)(7)(A) has been reviewed and deficiencies have been identified. The Pesticide Registration Improvement Act (PRIA) guarantees you a regulatory decision for the action category B880 of nine (9) months and the current decision date is March 30, 2009. By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified in this letter. However, there is not enough time remaining for you to submit the information requested above and for BPPD to complete the review necessary to make a favorable registration decision.

Therefore, you may negotiate the PRIA due date, withdraw the application and resubmit when you have all the information, or the Agency will issue a cannot grant letter under PRIA on or about March 30, 2009. You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application because it is incomplete.

If the Agency issues a letter stating it cannot grant your application under PRIA and you submit the required information within 75 days, the Agency will continue to work on your application, but it will not be subject to the PRIA time frame. Please contact Mike Mendelsohn immediately or within one (1) day from the date of this letter at (703) 308-8715 with your

SYMBOL	response.	7511P						
SURNAME	Mendelsohn	Ruff						112
DATE	3/19/09	3/19/09						

The deficiencies identified in the Agency's review follow.

- 1) At the present time, BPPD cannot accept the proposed use of a 5% refuge for corn rootworm (CRW) for SmartStax. While the Monsanto/Dow proposal for reducing the CRW refuge from the 20% required for single trait CRW products presents a good case, BPPD is concerned that the models used to assess the durability of 5% refuge included unrealistic dose estimates for the SmartStax toxins (Cry3Bb1 and Cry34/35).
- 2) To address BPPD's concerns over the CRW dose assumptions, Monsanto/Dow can either: a) provide additional information to justify the current dose assumptions, or b) conduct additional model simulations using lower dose estimates. BPPD recommends dose levels of 85-95% for the single trait PIPs and 90-97% for the pyramid (SmartStax).
- 3) The following areas also need to be addressed to provide additional support for the proposal. These areas include:
 - Not all of the model simulations were conducted to compare 5% vs. 20% refuge for SmartStax; most simulations assumed a 5% refuge for MON 89034. As such it is difficult to assess the value (or risk) of 5% refuge relative to 20% refuge (or other sizes). Additional simulations including 5, 10, and 20% refuges would be useful for comparative purposes.
 - Recent selection experiments (i.e. Meihls et al. 2008) suggest that resistance could evolve quickly with non-recessive inheritance. BPPD believes the models could be adjusted to account for these and other similar findings. For example, Storer's stochastic model could include resistance allele frequencies > 0.001 .
- 4) Within the product characterization data submitted, the discrepancy between the size of the *SacI* fragment indicated by the plasmid map of PHP 17661 and the *cry34Ab1* positive band in the Southern blot must be satisfactorily explained.

We note that both glyphosate and glufosinate herbicide products used to control weeds in corn must have product labeling approved by the Office of Pesticide Programs' Registration Division allowing their combined use on corn before such combined use is implemented by pesticide users in the field.

If you have any questions regarding this letter, please do not hesitate to contact Mike Mendelsohn of my staff, (703) 308-8715 (mendelsohn.mike@epa.gov), or me, (703) 308-8269 (reilly.sheryl@epa.gov).

Sincerely,



Sheryl Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures

cc: Dan Kenny, Chief, Herbicide Branch



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 16, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-394799
EPA File Symbol or Registration Number: 524-LIR
Product Name: MON 8903 X TC1507XMON 88017 X DAS 59122-7
EPA Receipt Date: 12-Jun-2008
EPA Company Number: 524
Company Name: MONSANTO COMPANY

RUSSELL P. SCHNEIDER
MONSANTO CO
MONSANTO COMPANY
1300 I STREET, NW, SUITE 450 EAST
WASHINGTON, DC 20005

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B880

NEW PRODUCT;NO SAP REQUIRED;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8260.

Sincerely,

Teresa Downs

Front End Processing Staff
Information Technology & Resources Management Division

115

Fee for Service

{8309919~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay ☒ % Reduction: ____

for Division

☐ AD

☒ BPPD

☐ RD

Risk Mgr.

92

Receipt No.

S-

830991

EPA File Symbol/Reg. No.

524-LIR

Pin-Punch Date:

6/12/2008

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

B880

Granted:

B880

Amount Due: \$ prepaid
\$ 26,250

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer:

Theresa Kelly

Date:

6/13/08

Remarks:

Receipt for Section 3

S: 830991

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 524 MONSANTO COMPANY

V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 92

Product #: 524-LIR Product Name: MON 8903 X TC1507XMON 88017 X DAS 591

Override#:

Me Too

Me Too

Section3:

Product Name:

Application Date: 11-Jun-2008

id

OPP Rec'd Date: 12-Jun-2008

id

Front End Date: 13-Jun-2008

id

Risk Manager Send Date:

id

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content

Study

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Application to register the plant-incorporated protectant *Bacillus thuringiensis*

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

FEE FOR SERVICE

Monsanto Company

NON NEGOTIABLE

1801229869

Accounts Payable Inquiries 314-694-2099, 800 N. Lindbergh, St. Louis, MO 63167

05/28/2008

Vendor Number: 371010

Invoice Number	Date	Gross Amount	Discount/Wthld	Net Amt	Comments
LLAIR0508200	05/08/2008	26,250.00	0.00	26,250.00	EPA Registration Fee MON89034 EPA524-575
Sum Total		26,250.00	0.00	26,250.00	

REMITTANCE ADVICE: The attached check is in full payment of invoices or other charges listed.

Sales or other Commercial/Financial Information is Not Included

CHECK HAS A GREEN BACKGROUND • WATERMARK • MICRO PRINT ON BACK • DO NOT CASH IF ALL ARE NOT PRESENT

62-20/311

MONSANTO**Monsanto Company**Accounts Payable Inquiries 314-694-2099
800 North Lindbergh, Saint Louis, MO 63167**1801229869**

DATE 05/28/2008

VOID IF NOT CASHED WITHIN SIX MONTHS

PAY TO THE
ORDER OFENVIRONMENTAL PROTECTION AGENCY
HQ ACCOUNTING OPERATIONS BRANCH
PM-226
PO Box 360399M
PITTSBURGH PA 15251-6399

*****26,250.00*

THIS AMOUNT *TWENTY-SIX THOUSAND TWO HUNDRED FIFTY***** USD

PAYABLE AT

CITIBANK, N.A.
ONE PENNS WAY
19720 NEW CASTLE, DE 19720by Tenell K. Crum
by Scott C. Kelly
Authorized Signatures

119

1801229869

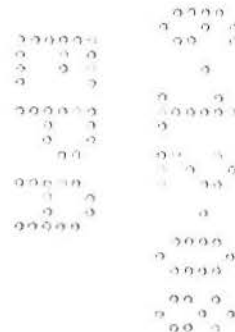
<div style="display: inline-block; text-align: center; margin-left: 20px;"> United States Environmental Protection Agency Washington, DC 20460 </div>		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide – Section I			
1. Company/Product Number File Symbol 524- XXX HR LIR		2. EPA Product Manager Sheryl Reilly	
Company/Product (Name) MON 89034 × TC1507 × MON 88017 × DAS-59122-7		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
Section – II			
<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification – Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input checked="" type="checkbox"/> Other – Explain below.	
Explanation: Use additional page(s) if necessary. (For Section I and Section II.) Application to Register the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, Cry3Bb1, Cry1F, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PV-ZMIR39, PHP8999, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7			
Section – III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. No. per Container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Various	
5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	
Section – IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Russell P. Schneider		Title Director, Regulatory Affairs	
		Telephone No. (Include Area Code) (202) 383-2866	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Affairs Manager	
4. Typed Name J. Austin Burns Tel. (314) 694-6514		5. Date June 11, 2008	



MONSANTO COMPANY
800 NORTH LINDBERGH BLVD
ST. LOUIS, MISSOURI 63167
<http://www.monsanto.com>

June 11, 2008

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501



Attn: Dr. Sheryl Reilly, Team Leader 92

Subject: Application for the registration of the combined plant-incorporated protectants, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (EPA File Symbol 524-XXX)

Dear Dr. Reilly:

Please find enclosed an application for the registration of the combined plant-incorporated protectants, *Bacillus thuringiensis* (Bt) Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins and the genetic material necessary for their production (PV-ZMIR245, PHP8999, PV-ZMIR39, PHP17662) produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (EPA File Symbol 524-XXX).

Monsanto Company and Dow AgroSciences have used conventional breeding techniques to develop the combined trait corn product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 that confers multiple modes of insect control. Each single product contributes specific benefits to the combined product. MON 89034 produces two Bt proteins, Cry2Ab2 (subsp. *kurstaki*) and Cry1A.105, a modified Cry1A Bt protein that protect against feeding damage caused by European corn borer (*Ostrinia nubilalis*) and other lepidopteran insect pests. MON 89034 was registered by Monsanto (EPA Reg. No. 524-575), in June 2008. TC1507 produces the Bt var *aizawai* Cry1F protein to selectively control larvae of the European corn borer (*Ostrinia nubilalis*) and other lepidopteran insect pests. TC1507 was registered by Dow/Mycogen (EPA Reg. No. 68467-2), in May 2001. MON 88017 produces a modified Bt (subsp. *kumamotoensis*) Cry3Bb1 protein to protect against corn rootworm (CRW) larval feeding. MON 88017 was registered by Monsanto (EPA Reg. No. 524-551), in December 2005. DAS-59122-7 produces

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the Bt strain PS149B1 Cry34Ab1 and Cry35Ab1 proteins to protect against corn rootworm. DAS-59122-7 registered by Dow AgroSciences (EPA Reg. No. 68467-5) in August 2005.

EPA has registered the Cry1A.105, Cry1F, Cry2Ab2, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins as produced in corn. The environmental and human safety of these proteins has been demonstrated and the EPA established an exemption from the requirement of a tolerance in corn as follows: Cry1A.105 protein, 40 CFR § 174.502, in 2008; Cry2Ab2, 40 CFR § 174.503, in 2008; Cry1F 40 CFR § 174.520, in 2001; Cry3Bb1, 40 CFR § 174.518, in 2004; and Cry34Ab1/Cry35Ab1, 40 CFR § 174.506, in 2005. The CP4 EPSPS and PAT proteins also produced by these events are classified as plant pesticide inert ingredients and are exempt from the requirement of a tolerance (40 CFR § 174.523, 40 CFR § 174.522, respectively).

Monsanto is therefore requesting that EPA grant a FIFRA Section 3 registration for MON 89034 × TC1507 × MON 88017 × DAS-59122-7, with a 5% structured refuge in the U.S. Corn Belt and a 20% structured refuge in cotton growing regions where corn earworm (*Helicoverpa zea*) is an important pest of corn and/or cotton. Commercial grower hybrid seed of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 will be produced through conventional breeding of two registered products, TC1507 × DAS-59122-7 and MON 89034 × MON 88017. Therefore, at this time, the registration request does not include any additional combinations of these four events.

Attached are letters from Pioneer Hi-Bred International and Dow AgroSciences authorizing data citation related to Events TC1507 and DAS-59122-7.

The documents accompanying this submission are listed in the table below. The table includes the classification categories "A", "B", and "C" for each document, as defined by the Agency:

- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).
- Category "C": Confidential Business Information that is protected from any disclosure indefinitely by provisions put forth by the EPA, as per FIFRA Section 10.

A CD-ROM containing the fully releasable ("A") documents, with the exception of the data citation authorization letters, is provided in .pdf format.

It is Monsanto's understanding that the following fee category and amount is appropriate based on the PRIA II Fee Table, effective October 1, 2007.

- Fee category: B880. New Product; no SAP review required
- Fee category amount: \$26,250

Documents accompanying this application for registration

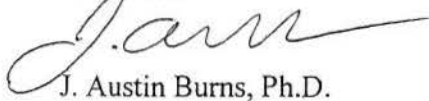
Volume	Category	Document	Hard copy	.pdf file for E-docket
N/A	A	Cover letter	√	√
N/A	A	Pioneer Hi-Bred data citation letter	√	
N/A	A	Dow AgroSciences data citation letter	√	
N/A	A	Transmittal document	√	√
1	A	Administrative volume (redacted copy)		√
1	B	Administrative volume	√	
1	C	Confidential Statement of Formula	√	
2	B	Human Health and Environmental Assessment of the Plant-Incorporated Protectant <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins Produced in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7.	√	
3	B	Summary of Southern Blot Analyses to Confirm the Presence of MON 89034, TC1507, MON 88017, and DAS-59122-7 in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7.	√	
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3b	B	Southern Blot Analyses to Confirm the Presence of TC1507 and DAS-59122-7 in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7.	√	
4	B	Summary of Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, CP4 EPSPS, Cry34Ab1, Cry35Ab1 and PAT Protein Levels in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Produced in US Field Trials in 2006.	√	

Documents accompanying this application for registration (continued)

Volume	Category	Document	Hard copy	.pdf file for E-docket
4a	B	Assessment of Cry1A.105, Cry2Ab2, Cry3Bb1, and CP4 EPSPS Protein Levels in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7.	√	
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5	B	Studies Performed to Evaluate the Potential for Interactions among Cry Proteins Produced by MON 89034 × TC1507 × MON 88017 × DAS-59122-7.	√	
5a	B	Evaluation of Potential for Interaction Between the <i>Bacillus thuringiensis</i> Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins.	√	
5b	B	Evaluation of the Potential for Interactions among Cry Proteins Produced by MON 89034 × TC1507 × MON 88017 × DAS-59122-7 by Insect Bioassay.	√	
6	B	Insect Resistance Management Plan for MON 89034 × TC1507 × MON 88017 × DAS-59122-7.	√	
7	B	Endangered Species Impact Assessment for the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7.	√	
8	B	Evaluation of Potential Dietary Effects of Pollen From the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 on the Ladybird Beetle <i>Coleomegilla maculata</i> (Coleoptera: Coccinellidae).	√	

Should you require any additional information regarding this application please feel free to contact Dr. Russell Schneider at 202-383-2866, or myself at 314-694-6514.

Sincerely,



J. Austin Burns, Ph.D.
Regulatory Affairs Manager
Monsanto Company

cc: Mike Mendelson, EPA/OPP/BPPD
Russell Schneider, Monsanto
Penny Hunst, Dow AgroSciences
Laura Tagliani, Dow AgroSciences

LIST OF SUBMITTED DOCUMENTS

Administrative Materials

- Volume 1.** Administrative Materials for the Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17622) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7

MRID Number _____

Product Summary

- Volume 2.** Burns, J.A. 2008. Human Health and Environmental Assessment of the Plant-Incorporated Protectant *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins Produced in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical report MSL0021223.

MRID Number 47444901

Product Characterization

- Volume 3.** Rice, J.F. 2008. Summary of Southern Blot Analyses to Confirm the Presence of MON 89034, TC1507, MON 88017, and DAS-59122-7 in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021265.

MRID Number 47444902

- Volume 3a.** Taylor, J.P., J.R Groat, and J.D Masucci. 2007. Southern Blot Analyses to Confirm the Presence of MON 89034 and MON 88017 in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0020682.

MRID Number 47444903

- Volume 3b.** Schafer, B.W., C. Q. Cia, and S.K. Embrey. 2008. Southern Blot Analyses to Confirm the Presence of TC1507 and DAS-59122-7 in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Dow AgroSciences Study ID 071179.

MRID Number 47444904

- Volume 4.** Murphy, J.A. and J.S. McClain. 2008. Summary of Cry1A.105, Cry2Ab2, Cry1F Cry3Bb1, CP4 EPSPS, Cry34Ab1, Cry35Ab1 and PAT Protein Levels in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Produced in US Field Trials in 2006. Monsanto Technical Report MSL0021266.

MRID Number 47444905

- Volume 4a.** Stillwell, L. and A. Silvanovich. 2007. Assessment of Cry1A.105, Cry2Ab2, Cry3Bb1, and CP4 EPSPS Protein Levels in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021070.

MRID Number 47444906

- Volume 4b.** Phillips, A.M. 2008. Cry34Ab1, Cry35Ab1, Cry1F, and PAT Protein Levels in Hybrid Maize TC1507, DAS-59122-7, MON 89034 × TC1507 × MON 88017 × DAS-59122-7, and a Conventional Control from the Monsanto 2006 Production Plan 06-01-52-04. Dow AgroSciences Study ID 061026.06.

MRID Number 47444907

Protein Interaction

- Volume 5.** Levine, S. 2008. Studies Performed to Evaluate the Potential for Interactions among Cry Proteins Produced by MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021267.

MRID Number 47444908

- Volume 5a.** MacRae, T. 2008. Evaluation of Potential for Interaction Between the

Bacillus thuringiensis Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins.
Monsanto Technical Report MSL0020554.

MRID Number 47444909

Volume 5b. Levine, S. 2008. Evaluation of the Potential for Interactions among Cry Proteins Produced by MON 89034 × TC1507 × MON 88017 × DAS-59122-7 by Insect Bioassay. Monsanto Technical Report MSL0021104.

MRID Number 47444910

Insect Resistance Management

Volume 6. Head, G. and N. Storer. 2008. Insect Resistance Management Plan for MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021285.

MRID Number 47444911

Endangered Species Risk Assessment

Volume 7. Levine, S. and J. Huesing. 2008. Endangered Species Impact Assessment for the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021268.


MRID Number 47444912

Non-Target Organism Study

Volume 8. Paradise, M. 2008. Evaluation of Potential Dietary Effects of Pollen From the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 on the Ladybird Beetle *Coleomegilla maculata* (Coleoptera: Coccinellidae). Monsanto Technical Report MSL0021036

MRID Number 47444913

128


J. Austin Burns, Ph.D.

6-11-2008

Date _____

J. Austin Burns, Ph.D.
Regulatory Affairs Manager
(314) 694-6514

Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.
Senior Director, Regulatory Affairs and Policy
(202) 383-2866

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MONSANTO
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MONSANTO COMPANY
800 NORTH LINDBERGH BLVD
ST. LOUIS, MISSOURI 63167
<http://www.monsanto.com>

June 11, 2008

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Subject: Application for the registration of the combined plant-incorporated protectants, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (EPA File Symbol 524-XXX)

Dear Dr. Reilly:

Please find enclosed an application for the registration of the combined plant-incorporated protectants, *Bacillus thuringiensis* (Bt) Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins and the genetic material necessary for their production (PV-ZMIR245, PHP8999, PV-ZMIR39, PHP17662) produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (EPA File Symbol 524-XXX).

Monsanto Company and Dow AgroSciences have used conventional breeding techniques to develop the combined trait corn product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 that confers multiple modes of insect control. Each single product contributes specific benefits to the combined product. MON 89034 produces two Bt proteins, Cry2Ab2 (subsp. *kurstaki*) and Cry1A.105, a modified Cry1A Bt protein that protect against feeding damage caused by European corn borer (*Ostrinia nubilalis*) and other lepidopteran insect pests. MON 89034 was registered by Monsanto (EPA Reg. No. 524-575), in June 2008. TC1507 produces the Bt var *aizawai* Cry1F protein to selectively control larvae of the European corn borer (*Ostrinia nubilalis*) and other lepidopteran insect pests. TC1507 was registered by Dow/Mycogen (EPA Reg. No. 68467-2), in May 2001. MON 88017 produces a modified Bt (subsp. *kumamotoensis*) Cry3Bb1 protein to protect against corn rootworm (CRW) larval feeding. MON 88017 was registered by Monsanto (EPA Reg. No. 524-551), in December 2005. DAS-59122-7 produces

the Bt strain PS149B1 Cry34Ab1 and Cry35Ab1 proteins to protect against corn rootworm. DAS-59122-7 registered by Dow AgroSciences (EPA Reg. No. 68467-5) in August 2005.

EPA has registered the Cry1A.105, Cry1F, Cry2Ab2, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins as produced in corn. The environmental and human safety of these proteins has been demonstrated and the EPA established an exemption from the requirement of a tolerance in corn as follows: Cry1A.105 protein, 40 CFR § 174.502, in 2008; Cry2Ab2, 40 CFR § 174.503, in 2008; Cry1F 40 CFR § 174.520, in 2001; Cry3Bb1, 40 CFR § 174.518, in 2004; and Cry34Ab1/Cry35Ab1, 40 CFR § 174.506, in 2005. The CP4 EPSPS and PAT proteins also produced by these events are classified as plant pesticide inert ingredients and are exempt from the requirement of a tolerance (40 CFR § 174.523, 40 CFR § 174.522, respectively).

Monsanto is therefore requesting that EPA grant a FIFRA Section 3 registration for MON 89034 × TC1507 × MON 88017 × DAS-59122-7, with a 5% structured refuge in the U.S. Corn Belt and a 20% structured refuge in cotton growing regions where corn earworm (*Helicoverpa zea*) is an important pest of corn and/or cotton. Commercial grower hybrid seed of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 will be produced through conventional breeding of two registered products, TC1507 × DAS-59122-7 and MON 89034 × MON 88017. Therefore, at this time, the registration request does not include any additional combinations of these four events.

Attached are letters from Pioneer Hi-Bred International and Dow AgroSciences authorizing data citation related to Events TC1507 and DAS-59122-7.

The documents accompanying this submission are listed in the table below. The table includes the classification categories "A", "B", and "C" for each document, as defined by the Agency:

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A CD-ROM containing the fully releasable ("A") documents, with the exception of the data citation authorization letters, is provided in .pdf format.

It is Monsanto's understanding that the following fee category and amount is appropriate based on the PRIA II Fee Table, effective October 1, 2007.

- Fee category: B880. New Product; no SAP review required
- Fee category amount: \$26,250

Documents accompanying this application for registration

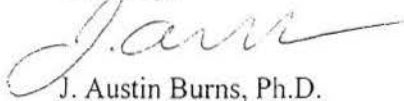
Volume	Category	Document	Hard copy	.pdf file for E-docket
N/A	A	Cover letter	√	√
N/A	A	Pioneer Hi-Bred data citation letter	√	
N/A	A	Dow AgroSciences data citation letter	√	
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Documents accompanying this application for registration (continued)

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5	B	Studies Performed to Evaluate the Potential for Interactions among Cry Proteins Produced by MON 89034 × TC1507 × MON 88017 × DAS-59122-7.	√	
5a	B	Evaluation of Potential for Interaction Between the <i>Bacillus thuringiensis</i> Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins.	√	
5b	B	Evaluation of the Potential for Interactions among Cry Proteins Produced by MON 89034 × TC1507 × MON 88017 × DAS-59122-7 by Insect Bioassay.	√	
6	B	Insect Resistance Management Plan for MON 89034 × TC1507 × MON 88017 × DAS-59122-7.	√	
7	B	Endangered Species Impact Assessment for the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7.	√	
8	B	Evaluation of Potential Dietary Effects of Pollen From the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 on the Ladybird Beetle <i>Coleomegilla maculata</i> (Coleoptera: Coccinellidae).	√	

Should you require any additional information regarding this application please feel free to contact Dr. Russell Schneider at 202-383-2866, or myself at 314-694-6514.

Sincerely,



J. Austin Burns, Ph.D.
Regulatory Affairs Manager
Monsanto Company

cc: Mike Mendelson, EPA/OPP/BPPD
Russell Schneider, Monsanto
Penny Hunst, Dow AgroSciences
Laura Tagliani, Dow AgroSciences

LIST OF SUBMITTED DOCUMENTS

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Product Summary

- Volume 2.** Burns, J.A. 2008. Human Health and Environmental Assessment of the Plant-Incorporated Protectant *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins Produced in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical report MSL0021223.

MRID Number _____

Product Characterization

- Volume 3.** Rice, J.F. 2008. Summary of Southern Blot Analyses to Confirm the Presence of MON 89034, TC1507, MON 88017, and DAS-59122-7 in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021265.

MRID Number _____

- Volume 3a.** Taylor, J.P., J.R Groat, and J.D Masucci. 2007. Southern Blot Analyses to Confirm the Presence of MON 89034 and MON 88017 in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0020682.

MRID Number _____

- Volume 3b.** Schafer, B.W., C. Q. Cia, and S.K. Embrey. 2008. Southern Blot Analyses to Confirm the Presence of TC1507 and DAS-59122-7 in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Dow AgroSciences Study ID 071179.

MRID Number _____

- Volume 4.** Murphy, J.A. and J.S. McClain. 2008. Summary of Cry1A.105, Cry2Ab2, Cry1F Cry3Bb1, CP4 EPSPS, Cry34Ab1, Cry35Ab1 and PAT Protein Levels in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Produced in US Field Trials in 2006. Monsanto Technical Report MSL0021266.

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- Volume 4b.** Phillips, A.M. 2008. Cry34Ab1, Cry35Ab1, Cry1F, and PAT Protein Levels in Hybrid Maize TC1507, DAS-59122-7, MON 89034 × TC1507 × MON 88017 × DAS-59122-7, and a Conventional Control from the Monsanto 2006 Production Plan 06-01-52-04. Dow AgroSciences Study ID 061026.06.

MRID Number _____

Protein Interaction

- Volume 5.** Levine, S. 2008. Studies Performed to Evaluate the Potential for Interactions among Cry Proteins Produced by MON 89034 × TC 1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021267.

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Monsanto Technical Report MSL0020554.

MRID Number _____

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MRID Number _____

Insect Resistance Management

- Volume 6.** Head, G. and N. Storer. 2008. Insect Resistance Management Plan for MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021285.

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Endangered Species Risk Assessment

- Volume 7.** Levine, S. and J. Huesing. 2008. Endangered Species Impact Assessment for the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021268.

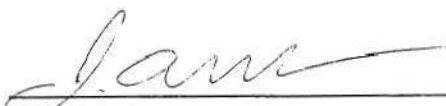
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Non-Target Organism Study

- Volume 8.** Paradise, M. 2008. Evaluation of Potential Dietary Effects of Pollen From the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 on the Ladybird Beetle *Coleomegilla maculata* (Coleoptera: Coccinellidae). Monsanto Technical Report MSL0021036.

MRID Number _____

Company Official:


J. Austin Burns, Ph.D.
Regulatory Affairs Manager
(314) 694-6514

6-11-2008

Date

Company Name:

Monsanto Company

Company Contact:

Russell P. Schneider, Ph.D.
Senior Director, Regulatory Affairs and Policy
(202) 383-2866



April 11, 2008

Document Processing Desk
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22022-4501

Attn: Dr. Janet Andersen, Director Biopesticide and Pollution Prevention Division

LETTER AUTHORIZING DATA CITATION

We hereby confirm that Agrigenetics d/b/a Mycogen Plant Sciences c/o Dow AgroSciences LLC and its affiliates (collectively, "Dow AgroSciences") authorizes Monsanto Company to cite and the U.S. Environmental Protection Agency to refer to data previously submitted by Dow AgroSciences in connection with any of the following products:

- *Insect-protected, glufosinate-tolerant maize containing the Cry1F and PAT proteins, Event TC1507 (DAS-01507-1);*
- *Insect-protected, glufosinate-tolerant maize containing the Cry34/35Ab1 and PAT proteins, Event DAS-59122-7 (DAS-59122-7)*

for the purpose of evaluating and issuing a Section 3 registration to Monsanto Company for the combined trait product MON 89034 x TC1507 x MON 88017 x DAS-59122-7.

This authorization shall not be construed as authorization to use or consider said data, directly or indirectly, in support of any application submitted by any other applicant, for an application by Monsanto Company for activities other than a registration request described herein, or for any other regulatory entity to refer to or rely on this data. Dow AgroSciences does not grant permission for citation or reference of this data for any use not specifically stated herein, does not grant permission for citation or reference of data (including future data) not specified herein, and nothing in this agreement grants permission for the U.S. EPA to provide copies of any data to any party.



DuPont Agriculture & Nutrition
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7250 N.W. 82nd Ave.
P.O. Box 552
Johnston, IA 50131-0552
(515) 270-3200 Tel

Letter of Authorization to Refer to Regulatory Data

We hereby confirm that Pioneer, on behalf of itself and its Affiliates, (collectively, "Pioneer") authorizes U.S. EPA regulatory agency to refer to data previously submitted by Pioneer in connection with any of the following products:

- *Insect-Protected, Glufosinate-Tolerant maize containing the B.t. Cry1F protein (Bacillus thuringiensis var aizawai Cry1F protein) and the PAT protein (Streptomyces viridochromogenes phosphinothricin acetyltransferase) Event TC1507 (DAS-01507-1);*
- *Insect-Protected, Glufosinate-Tolerant maize containing the B.t. Cry34/35Ab1 protein (Cry34Ab1 and Cry35Ab1 proteins) and the PAT protein (Streptomyces viridochromogenes phosphinothricin acetyltransferase) Event DAS-59122 (DAS-59122-7);*
- for the purpose of obtaining regulatory or governmental approval or clearance for Monsanto by U.S. EPA (regulatory agency) of or for a transgenic maize crop, including any breeding stacks containing the above referenced products in combination with any other trait or traits.

We further authorize Monsanto to present this letter to all competent regulatory authorities in connection with seeking such approvals and authorize all such regulatory authorities to rely on this letter.

This authorization shall not be construed as authorization to use or consider said data, directly or indirectly, in support of any application submitted by any other applicant. Pioneer does not release any data for any use not specifically stated herein.

If you require further information, please contact the undersigned at 515-270-3997.

Sincerely,

John H. Duesing
Senior Research Director
Pioneer Hi-Bred International

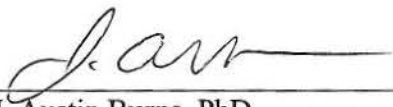
The text below applies only to use of the data by the United States Environmental Protection Agency (U.S. EPA) in connection with the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

STATEMENT OF DATA CONFIDENTIALITY CLAIM

No claim of data confidentiality is being made for information contained in this document on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C). However, a supplemental data confidentiality claim is being made for some information claimed herein. The applicable information has been removed to a confidential attachment.

“We submit this material to the United States Environmental Protection Agency specifically under requirements set forth in FIFRA as amended, and consent to use and disclosure of this material by the EPA strictly in accordance with FIFRA. By submitting this material to EPA in accordance with the method and format requirements contained in PR Notice 86-5, we reserve and do not waive any rights involving this material that are or can be claimed by the company notwithstanding this submission to the EPA.”

COMPANY: Monsanto Company

COMPANY AGENT: 
J. Austin Burns, PhD.
Regulatory Affairs Manager

DATE: June 11, 2008

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GLP COMPLIANCE STATEMENT

The materials in this volume do not meet the requirements of the Good Laboratory Practice Standards, 40 CFR Part 160. This volume provides the administrative materials for the application to register the plant-incorporated protectants, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 proteins, and the genetic materials (vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17622) necessary for their production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, and therefore were not developed in compliance with 40 CFR Part 160.



Submitter

J. Austin Burns, PhD.

Regulatory Affairs Manager

6-11-2008

Date



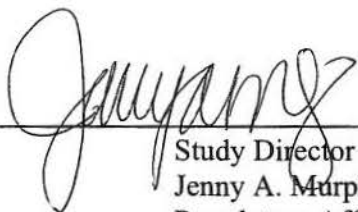
Sponsor

Linda K. Lahman

Lead, Corn Regulatory Affairs

6-11-08

Date



Study Director

Jenny A. Murphy

Regulatory Affairs Manager

6/11/2008

Date

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VOLUME 1

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ABBREVIATIONS AND DEFINITIONS

Bt	<i>Bacillus thuringiensis</i>
CBI	Confidential business information
CFR	U.S. Code of Federal Regulations
CSF	Confidential Statement of Formula
Cry1A.105	A chimeric protein comprised of sequences from the naturally occurring Cry1Ab, Cry1F, and Cry1Ac proteins from <i>Bacillus thuringiensis</i>
Cry1F	An insecticidal crystal protein derived from <i>Bacillus thuringiensis</i> var <i>aizawai</i> .
Cry2Ab2	A crystal protein derived from <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i>
Cry3Bb1	A Class III (Coleoptera-specific) crystal protein from <i>Bacillus thuringiensis</i> subsp <i>kumamotoensis</i>
Cry34Ab1	An insecticidal crystal protein (Coleopteran-specific) from <i>Bacillus thuringiensis</i> strain PS149B1
Cry34/35Ab1	Binary insecticidal crystal protein (Coleoptera-specific) from <i>Bacillus thuringiensis</i> strain PS149B1
Cry35Ab1	An insecticidal crystal protein (Coleoptera-specific) from <i>Bacillus thuringiensis</i> strain PS149B1
DAS-59122-7	Corn event expressing the Cry34Ab1, Cry35Ab1 and PAT proteins
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
IRM	Insect resistance management
MON 89034	A corn product that produces the insecticidal <i>Bacillus thuringiensis</i> Cry1A.105 and Cry2Ab2 proteins
MON 89034 × TC107 × MON 88017 × DAS-59122-7	A combined trait corn product, and the subject of this application for registration, that produces the insecticidal <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, Cry1F, Cry34/35Ab1 proteins
MON 88017	A corn product that produces the insecticidal <i>Bacillus thuringiensis</i> Cry3Bb1 protein
MRID	EPA master record identification number
NTO	Nontarget organism
PHP8999	Plasmid construct containing the <i>cry1F</i> and <i>pat</i> genes, and the genetic material necessary for their expression.
PHP17662	Plasmid construct containing the <i>cry34Ab1</i> , <i>cry35Ab1</i> , and <i>pat</i> genes and the genetic material necessary for their expression
PR Notice	EPA Pesticide Registration notice

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PV-ZMIR245

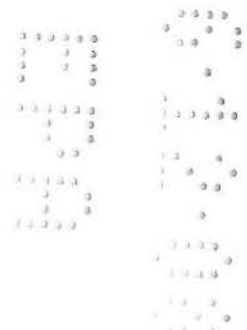
Deoxyribonucleic acid vector (genetic material) used in the transformation of corn to produce MON 89034

PV-ZMIR39

Deoxyribonucleic acid vector (genetic material) used in the transformation of corn to produce MON 88017

TC1507 (DAS- Ø15 Ø7-1)

Corn event expressing the Cry1F (Lepidoptera-specific) and PAT proteins



SECTION I

ADMINISTRATIVE MATERIALS

Application for Registration (Form 8570-1)

Confidential Statement of Formula (Form 8570-4)

Certification with Respect to Citation of Data (Form 8570-34)

Data Matrix (Form 8570-35)

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 (314) 694-6514	EPA Registration Number / File Symbol: 524-XXX
Active Ingredient(s) and/or representative test compound(s): <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/3Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7	Date: June 11, 2008
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: MON 89034 x TC1507 x MON 88017 x DAS-59122-7

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

Section II: GENERAL OFFER TO PAY

☐ [Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

Section III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature 	Date 6-11-2008	Typed or Printed Name and Title J. Austin Burns Regulatory Affairs Manager
---------------	-------------------	--

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DATA MATRIX


Date: June 11, 2008 EPA Reg. No./File Symbol: 524-XXX Page 1 of 56

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 × TC1507 × MON 88017 ×
DAS-59122-7

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034-3 × DAS-01507 × MON-88017-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34 and Cry35 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7.		Monsanto Company	OWN	This Application
885.1100	Burns, J.A. 2008. Human Health and Environmental Assessment of the Plant-Incorporated Protectant <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, Cry3Bb1, Cry1F, Cry34Ab1, and Cry35Ab1 Proteins Produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0020223.		Monsanto Company	OWN	Product Characterization This Application
885.1100	Rice, J.F. 2008. Summary of Southern Blot Analyses to Confirm the Presence of MON 89034, TC1507, MON 88017, and DAS-59122-7 in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021265.		Monsanto Company	OWN	Product Characterization This Application
885.1100	Taylor, J.P., J.R. Groat, and J.D. Masucci. 2007. Southern Blot Analyses to Confirm the Presence of MON 89034 and MON 88017 in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0020682.		Monsanto Company	OWN	Product Characterization This Application
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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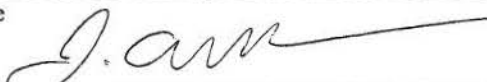


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DATA MATRIX

Date: June 11, 2008		EPA Reg. No./File Symbol: 524-XXX		Page 2 of 56	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7			
Ingredient <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034-3 × DAS-01507 × MON-88017-3 × DAS-59122-7)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Schafer, B.W., C. Q. Cia, and S.K. Embrey. 2008. Southern Blot Analyses to Confirm the Presence of TC1507 and DAS-59122-7 in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Dow AgroSciences Study ID 071179.		Monsanto Company	OWN	Product Characterization This Application
885.1100	Murphy, J.A. and J.S. McClain. 2008. Summary of Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, CP4 EPSPS, Cry34Ab1, Cry35Ab1 and PAT Protein Levels in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Produced in US Field Trials in 2006. Monsanto Technical Report MSL0021266.		Monsanto Company	OWN	Product Characterization This Application
885.1100	Stillwell, L. and A. Silvanovich. 2007. Assessment of Cry1A.105, Cry2Ab2, Cry3Bb1, and CP4 EPSPS Protein Levels in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021070.		Monsanto Company	OWN	Product Characterization This Application
885.1100	Phillips, A.M. 2008. Cry34Ab1, Cry35Ab1, Cry1F, and PAT Protein Levels in Hybrid Maize TC1507, DAS-59122-7, MON 89034 × TC1507 × MON 88017 × DAS-59122-7, and a Conventional Control from the Monsanto 2006 Production Plan 06-01-52-04. Dow AgroSciences Study ID 061026.06.		Monsanto Company	OWN	Product Characterization This Application
N/A	Levine, S. 2008. Studies Performed to Evaluate the Potential for Interactions among Cry Proteins Produced by MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021267.		Monsanto Company	OWN	Environmental Assessment This Application
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008



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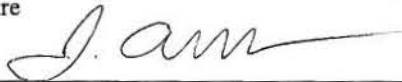
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DATA MATRIX

Date: June 11, 2008 EPA Reg. No./File Symbol: 524-XXX Page 3 of 56
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 Product: MON 89034 x TC1507 x MON 88017 x DAS-59122-7

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (OECD Unique Identifier: MON-89034-3 x DAS-01507 x MON-88017-3 x DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	MacRae, T. 2008. Evaluation of Potential for Interaction Between the <i>Bacillus thuringiensis</i> Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins. Monsanto Technical Report MSL0020554		Monsanto Company	OWN	Environmental Assessment This Application
N/A	Levine, S. 2008. Evaluation of the Potential for Interactions among Cry Proteins Produced by MON 89034 x TC1507 x MON 88017 x DAS-59122-7 by Insect Bioassay. Monsanto Technical Report MSL0021104.		Monsanto Company	OWN	Environmental Assessment This Application
N/A	Head, G. and N. Storer. 2008. Insect Resistance Management Plan for MON 89034 x TC1507 x MON 88017 x DAS-59122-7. Monsanto Technical Report MSL0021285.		Monsanto Company	OWN	IRM This Application
N/A	Levine, S. and J. Huesing. 2008. Endangered Species Impact Assessment for the Combined Trait Corn Product MON 89034 x TC1507 x MON 88017 x DAS-59122-7. Monsanto Technical Report MSL0021268.		Monsanto Company	OWN	Environmental Assessment This Application
885.4340	Paradise, M. 2008. Evaluation of Potential Dietary Effects of Pollen From the Combined Trait Corn Product MON 89034 x TC1507 x MON 88017 x DAS-59122-7 on the Ladybird Beetle <i>Coleomegilla maculata</i> (Coleoptera: Coccinellidae). Monsanto Technical Report MSL0021036.		Monsanto Company	OWN	Environmental Assessment This Application
Signature 		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008	

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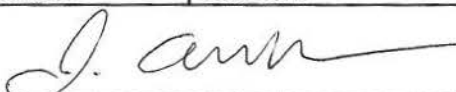
Date: June 11, 2008 EPA Reg. No./File Symbol: 524-575 Page 4 of 56

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3).		Monsanto Company	OWN	
885.1100	Bogdanova, N.N. 2006. Human Health and Environmental Assessment of the Plant-Incorporated Protectant <i>Bacillus thuringiensis</i> Cry1A.105 and Cry2Ab2 Proteins Produced in Corn MON 89034.	469514-01	Monsanto Company	OWN	Product Characterization
885.1100	Rice, J.F., B.J. Wolff, J.R. Groat, N.K. Scanlon, J.C. Jennings, and J.D. Masucci. 2006. Amended Report for MSL-20072: Molecular Analysis of Corn MON 89034. Monsanto Technical Report MSL-20311.	469514-02	Monsanto Company	OWN	Product Characterization
885.1100	Hartmann, A.J., K.E. Niemeyer, and A. Silvanovich. 2006. Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials. Monsanto Technical Report MSL-20285.	469514-03	Monsanto Company	OWN	Product Characterization
885.1100	Karunanandaa, K., J.J. Thorp, M.E. Goley, S.L. Levine, and A. Silvanovich. 2006. Characterization of the Cry2Ab2 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and <i>E. coli</i> -Produced Cry2Ab2 Proteins. Monsanto Technical Report MSL-20071.	469514-04	Monsanto Company	OWN	Product Characterization
Signature			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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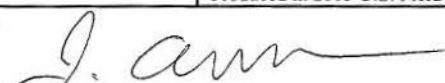
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DATA MATRIX

Date: June 11, 2008		EPA Reg. No./File Symbol: 524-575		Page 5 of 56	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034			
Ingredient <i>Bacillus thuringiensis</i> Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Levine, S.L. and J. Uffman. 2006. Evaluation of the Functional Equivalence of the Cry2Ab2 Protein Produced in <i>E.Coli</i> and <i>Bt</i> Against a Sensitive Lepidopteran Species. Monsanto Technical Report MSL-20132.	469514-05	Monsanto Company	OWN	Product Characterization
885.1100	Rice, J.F., B.J. Wolff, J.C. Jennings, and J.D. Masucci. 2005. Summary of Southern Blot Analysis of MON 89034 and MON 89597 Corn. Monsanto Technical Report MSL-20068	466945-01	Monsanto Company	OWN	Product Characterization
885.1100	Goertz, B., T. Ganguly, J. Lee, T. Lee, and E.A. Rice. 2005. Characterization of the Cry1A.105 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and <i>E.coli</i> -Produced Cry1A.105 Proteins. Monsanto Technical Report MSL-19960.	466946-04	Monsanto Company	OWN	Product Characterization
	Supplemental Information for MRID No. 46951402 "Amended Report for MSL-20072: Molecular analysis of Corn MON 89034".	471275-03	Monsanto Company	OWN	Product Characterization
	Supplemental Information for MRID No. 46951403 "Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials".	471275-05	Monsanto Company	OWN	Product Characterization
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008

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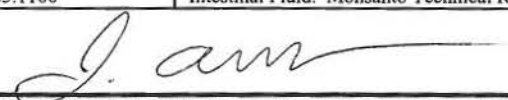
Date: June 11, 2008 EPA Reg. No./File Symbol: 524-575 Page 6 of 56

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Bogdanova, N.N. 2005. Structural and Functional Similarity of the Cry1A.105 Protein to Cry1A Class of <i>Bacillus thuringiensis</i> Proteins. Monsanto Technical Report 05-RA-62-01.	466946-01	Monsanto Company	OWN	Product Characterization
860.1340	Dudin, Y.A and P. Chinnadurai. 2005. Qualitative Detection Method for the Cry2Ab2 Protein in Corn Leaf and Seed of MON 89034 and MON 89597. Monsanto Technical Report 05-RA-39-04.	466945-03	Monsanto Company	OWN	Product Characterization
885.3050	Bonnette, K.L. 2006. An acute oral toxicity study in mice with Cry2Ab2 protein. Monsanto Study CRO-2005-049.	469514-06	Monsanto Company	OWN	Human Health Assessment
885.1100	Kapadia, S.A. and E.A. Rice. 2006. Assessment of the <i>in vitro</i> Digestibility of the Cry2Ab2 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19931.	469514-07	Monsanto Company	OWN	Human Health Assessment
885.1100	Kapadia, S. and E.A. Rice. 2005. Assessment of the <i>in vitro</i> Digestibility of the Cry1A.105 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSP-19930.	469514-08	Monsanto Company	OWN	Human Health Assessment
Signature 	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008		

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Date: June 11, 2008		EPA Reg. No./File Symbol: 524-575		Page 7 of 56	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034			
Ingredient <i>Bacillus thuringiensis</i> Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	McCoy, R.L. and A. Silvanovich. 2005. Bioinformatics Analysis of the Cry1A.105 Protein Utilizing the AD5, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-19686.	466946-05	Monsanto Company	OWN	Human Health Assessment
885.1100	Thorp, J.J. and M.E. Goley. 2006. Assessment of the <i>in vitro</i> Digestibility of the Cry2Ab2 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19938	469514-09	Monsanto Company	OWN	Human Health Assessment
885.1100	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Evaluation of the Cry1A.105 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20351.	469514-10	Monsanto Company	OWN	Human Health Assessment
885.1100	Kapadia, S.A. and E.A. Rice. 2005. Assessment of the <i>in vitro</i> Digestibility of the Cry1A.105 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19929.	466946-06	Monsanto Company	OWN	Human Health Assessment
885.1100	Goley, M.E. and J.J. Thorp. 2005. Immunodetection of Cry2Ab2 and Cry1A.105 Proteins in Corn Grain from MON 89034 Following Heat Treatment. Monsanto Technical Report MSL-19899.	466946-07	Monsanto Company	OWN	Human Health Assessment
885.3050	Bonnette, K.L. 2005. An Acute Oral Toxicity Study in Mice with Cry1A.105 Protein. Monsanto Study CRO-2005-050.	466946-03	Monsanto Company	OWN	Human Health Assessment
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008

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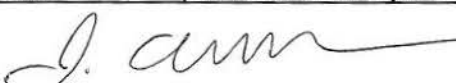


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Date: June 11, 2008		EPA Reg. No./File Symbol: 524-575		Page 8 of 56	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034			
Ingredient <i>Bacillus thuringiensis</i> Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Analysis of the Cry2Ab2 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20307.	469514-11	Monsanto Company	OWN	Human Health Assessment
885.4050	Davis, S.W. 2006. Comparison of Broiler Performance and Carcass Parameters When Fed Diets Containing MON 89034, Control or Commercial Corn. Monsanto Study 05-01-50-13, Amended Report.	469514-12	Monsanto Company	OWN	Human Health Assessment
N/A	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of <i>Bacillus thuringiensis</i> Cry1A.105 Protein. Monsanto Technical Report MSL-20230.	469514-13	Monsanto Company	OWN	Environmental Assessment
N/A	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of <i>Bacillus thuringiensis</i> Cry2Ab2 Protein. Monsanto Technical Report MSL-20229.	469514-14	Monsanto Company	OWN	Environmental Assessment
N/A	Headrick, J.M., O. Heredia, I.O. Oyediran, and T.T. Vaughn. 2006. Assessment of the Efficacy of Lepidopteran-protected Corn MON 89034 and MON 89597 Against Major Insect Pests in United States, Puerto Rico and Argentina During 2003-2004 Seasons. Monsanto Technical Report 05-RA-39-05.	469514-15	Monsanto Company	OWN	Environmental Assessment
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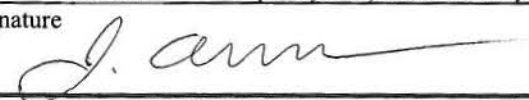
Date: June 11, 2008 EPA Reg. No./File Symbol: 524-575 Page 9 of 56

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Teixeira, D. 2006. Evaluation of Dietary Effects of Lyophilized Leaf Tissue from Corn MON 89034 in a Chronic Exposure Study with Collembola (<i>Folsomia candida</i>). Monsanto Technical Report MSL-20169.	469514-16	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S.J. and H.O. Krueger. 2006. Evaluation of Exposure to MON 89034 with the Cladoceran <i>Daphnia magna</i> : An acute static-renewal test with corn pollen. Monsanto Study WL-2005-011.	469514-17	Monsanto Company	OWN	Environmental Assessment
885.6200	Sindermann, A.B., J.R. Porsch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry1A.105 Protein in an Acute Study with the Earthworm in an Artificial Soil Substrate. Monsanto Technical Report MSL-20147.	469514-18	Monsanto Company	OWN	Environmental Assessment
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cry1A.105 Protein on Honeybee Larvae (<i>Apis mellifera</i> L.). Monsanto Study CA-2005-071.	469514-19	Monsanto Company	OWN	Environmental Assessment
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cry1A.105 Protein on Adult Honeybees (<i>Apis mellifera</i> L.). Monsanto Study CA-2005-072	469514-20	Monsanto Company	OWN	Environmental Assessment
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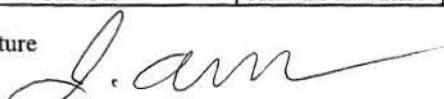
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry1A.105 Protein on the Ladybird Beetle, <i>Coleomegilla maculata</i> (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20150.	469514-21	Monsanto Company	OWN	Environmental Assessment
885.4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on the Ladybird Beetle, <i>Coleomegilla maculata</i> (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20151.	469514-22	Monsanto Company	OWN	Environmental Assessment
885.4340	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry1A.105 Protein on Minute Pirate Bugs, <i>Orius insidiosus</i> (Hemiptera: Anthocoridae). Monsanto Technical Report MSL-20170.	469514-23	Monsanto Company	OWN	Environmental Assessment
885.4340	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on Minute Pirate Bugs, <i>Orius insidiosus</i> (Hemiptera: Anthocoridae). Monsanto Technical Report MSL-20171.	469514-24	Monsanto Company	OWN	Environmental Assessment
885.4340	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry1A.105 Protein in an Acute Study with the Parasitic Wasp, <i>Ichneumon promissorius</i> (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20149.	469514-25	Monsanto Company	OWN	Environmental Assessment
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034			
Ingredient <i>Bacillus thuringiensis</i> Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4050	Gallagher, S.P. and J.B. Beavers. 2006. Evaluation of Potential Dietary Effects of MON 89034 with the Northern Bobwhite: an Eight-day Dietary Study with Corn Grain. Monsanto Technical Report WL-2005-012.	469514-27	Monsanto Company	OWN	Environmental Assessment
885.5200	Mueth, M., T. Curran, J. Warren, S. Dubelman, M. Glaspie, J. Murphy, S. Levine, J. Holtmeyer, and C. Jiang. 2006. Aerobic Soil Degradation of the Purified Cry2Ab2 and Cry1A.105 Proteins. Monsanto Technical Report MSL-20174.	469514-28	Monsanto Company	OWN	Environmental Assessment
N/A	Huesing, J.E., J.J. Duan, and S.L. Levine. 2006. Endangered Species Risk Assessment for Corn MON 89034. Monsanto Technical Report MSL0020394.	469514-29	Monsanto Company	OWN	Environmental Assessment
N/A	MacRae, T.C., C.R. Brown, S.L. Levine. 2005. Evaluation of the Potential for Interactions Between the <i>Bacillus Thuringiensis</i> Proteins Cry1A.105 and Cry2Ab2. Monsanto Technical Report MSL-19859.	466946-02	Monsanto Company	OWN	Environmental Assessment
885.4340	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry2Ab2 Protein in an Acute Study with the Parasitic Wasp, <i>Ichneumon promissorius</i> (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20148.	469514-26	Monsanto Company	OWN	Environmental Assessment
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034			
Ingredient <i>Bacillus thuringiensis</i> Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Palmer, S.J. and H.O. Krueger. 2000. Insect Protection Protein 2: An Acute Toxicity Study With the Earthworm in an Artificial Soil Substrate. Monsanto Technical Report MSL-16177	450863-13	Monsanto Company	OWN	Environmental Assessment
885.4380	Maggi, V.L. 2000. Evaluation of dietary effect(s) of purified <i>Bacillus thuringiensis</i> Cry2Ab2 protein on honey bee larvae. Monsanto Technical Report MSL-16961.	453371-02	Monsanto Company	OWN	Environmental Assessment
885.4340	Teixeira, D. 2000. Assessment of Chronic Toxicity of Cotton Tissue Containing Insect Protection Protein 2 to Collembola (<i>Folsomia candida</i>), Amended report. Monsanto Technical Report MSL-16174.	450863-14	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S. and H. Krueger. 2000. Insect Protection Protein 2: A Dietary Toxicity Study with Parasitic Hymenoptera (<i>Nasonia vitripennis</i>). Monsanto Technical Report MSL-16173.	450863-10	Monsanto Company	OWN	Environmental Assessment
885.4380	Maggi, V.L. 2000. Evaluation of the Dietary Effect(s) of Insect Protection Protein 2 on Adult Honey Bees (<i>Apis mellifera</i> L.). Monsanto Technical Report MSL-16176.	450863-08	Monsanto Company	OWN	Environmental Assessment
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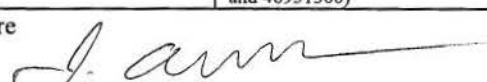
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Head, G. 2006. Insect Resistance Management Plan for Second Generation Lepidopteran-Protected Corn, MON 89034. Monsanto Technical Report 06-RA-39-06.	469514-30	Monsanto Company	OWN	IRM
	Bogdanova, N. and A. Crawford (2007). Public Interest Document Supporting Registration of <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2 and Cry3Bb1 Proteins in Insect-Protected Corn MON 89034 and MON 89034 x MON 88017	472797-01	Monsanto Company	OWN	Benefits
	Bogdanova, N., S. Dubelman, M. Mueth, J. Murphy and A. Silvanovich (2007). Responses to EPA Questions Regarding Application 524-LTL to register Insect-Protected Corn MON 89034 (MRID 46951428)	471403-01	Monsanto Company	OWN	Misc.
	Bogdanova, N., (2007) Responses to EPA Questions Regarding Applications 524-LTL and 524-LTL to Register Insect-Protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	471275-01	Monsanto Company	OWN	Misc.
	Bogdanova, N., (2007). Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTL to Register Insect-Protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	470794-02	Monsanto Company	OWN	Misc.
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient *B.t. Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)*

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Product Characterization Data for <i>Bacillus thuringiensis</i> var. <i>aizawai</i> Cry1F Insect Control Protein as expressed in Maize	447148-01	68467	PER	
	Characterization of Gene Inserts- <i>Bacillus thuringiensis</i> var. <i>aizawai</i> Cry1F Insect Control Proteins Expressed in Maize	447148-02	68467	PER	
	Equivalency of Microbial and Maize Expressed Cry1F Protein; Characterization of Test Substances for Biochemical and Toxicological Studies. In Vitro Digestibility of Microbial and Maize Expressed	447148-03	68467	PER	
	In Vitro Simulated Intestinal Fluid Digestibility Study of Microbially Derived Cry1F (tr)	N/A	68467	PER	
	Cry1F <i>B.t.</i> var <i>aizawai</i> Delta-endotoxin: Acute Oral Toxicity Study in Mice	446911-01	68467	PER	
Signature			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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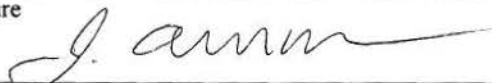


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Date: June 11, 2008		EPA Reg. No./File Symbol: 68467-2		Page 15 of 56	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: Herculex® I Insect Protection			
Ingredient B.t. Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Quantitative ELISA Analysis of Cry1F Expression levels in Maize MPS Inbred Lines 1360, 1365, 1366, and 1369. (Interim Report)	44714804	68467	PER	
	Effectiveness Data for Bacillus thuringiensis var. aizawai Cry1F Insect Control Protein as Expressed in Maize	44691102	68467	PER	
	Background Document on Resistance Management for Bacillus thuringiensis var. aizawai Cry1F Insect Control Protein as Expressed in MaizeCry1F Protein Under Simulated Gastric Conditions	44691103	68467	PER	
	Comparison of Amino Acid Sequence Similarity of Cry1F and PAT Proteins to Known Allergen Protein	44971701	68467	PER	
	Microbial B.t. Cry1F (truncated) Delta-Endotoxin: Maize-Insect-Pest Susceptibility Study	45020101	68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008

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DATA MATRIX

Date: June 11, 2008		EPA Reg. No./File Symbol: 68467-2		Page 16 of 56	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: Herculex® I Insect Protection			
Ingredient <i>B.t.</i> Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Characterization of Inserted Genes in Cry 1F Maize Line 1507	45020102	68467	PER	
	Characterization of Expressed Cry1F Protein in Maize Tissues (Pollen, Grain, Grain-Containing Feed, and Purified Maize-Expressed Cry1F Protein) and Microbial Expressed Cry1F Delta Endotoxin by Biological and Biochemical Procedures	45020103	68467	PER	
	Quantitative ELISA Analysis of Cry1F and PAT Expression levels in and Compositional Analysis of Maize Inbred and Hybrid Lines 1362 and 1507	45020104	68467	PER	
	Phosphinothricin acetyltransferase (PAT) protein: In Vitro Digestibility Study	45041501	68467	PER	
	Non-target Exposure and Risk Assessment for Environmental Dispersal of Cry1F Maize Pollen	45041502	68467	PER	
	Environmental Fate of Cry1F Protein incorporated into Soil	45020105	68467	PER	
Signature <i>J. Burns</i>		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008	

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Date: June 11, 2008		EPA Reg. No./File Symbol: 68467-2		Page 18 of 56	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: Herculex® I Insect Protection			
Ingredient B.t. Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Cry1F Binding Studies	45020115	68467	PER	
	Evaluation of the Dietary Effect(s) on Honeybee Development Using Bacterially Expressed B.t. Cry1F Delta-Endotoxin and Pollen from Maize Expressing B.t. Cry1F Delta Endotoxin	45041503	68467	PER	
	Cry1F Bacillus Thuringiensis var. Aizawai Delta Endotoxin: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate	45020106	68467	PER	
	Cry1F Bacillus Thuringiensis var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with Green Lacewing Larvae	45020109	68467	PER	
	Cry1F Bacillus Thuringiensis var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with the Ladybird Beetle	45020110	68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008

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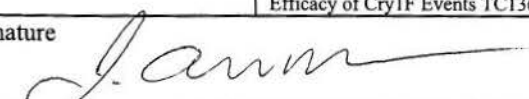


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Date: June 11, 2008		EPA Reg. No./File Symbol: 68467-2		Page 17 of 56	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: Herculex® I Insect Protection			
Ingredient <i>B.t. Cry1F</i> protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Chronic Exposure of Folsomia Candida to Bacterially Expressed Cry1F Protein	45020107	68467	PER	
	B.t. Cry1F Delta-Endotoxin: A 48-Hour Static-Renewal Acute Toxicity Test with the Cladoceran (Daphnia magna) Using Bacterially Expressed B.t. Cry1F Delta-Endotoxin, and Pollen from Maize Expressing B.t. Cry1F Delta-Endotoxin	45020108	68467	PER	
	Waiver Request: Fish Toxicity Text With Transgenic Maize (Corn) Containing Bacillus thuringiensis var. aizawai (B.t.) Cry1F Delta-Endotoxin Delta-Endotoxin	45044201	68467	PER	
	Field Survey of Beneficial Arthropods Associated with Bacillus thuringiensis Cry1F Maize	45020113	68467	PER	
	Efficacy of Cry1F Events TC1360 and TC1507	45020114	68467	PER	
Signature 		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008	

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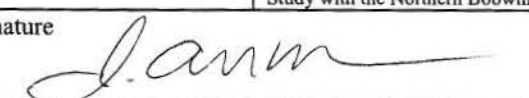
Page 19 of 56

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient B.t. Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Cry1F Bacillus Thuringiensis var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with Parasitic Hymenoptera	45020111	68467	PER	
	Supplement to MRID 44691101: Supplemental Data for Acute Oral Toxicity Study in Mice: Cry1F Bacillus thuringiensis var. aizawai delta-endotoxin	45020118	68467	PER	
	Characterization of Inserted Genes in Cry1F Maize Line 1507	45010102	68467	PER	
	Resistance Management Plan for Transgenic Maize Expressing the Cry1F Insecticidal Protein from Bacillus thuringiensis var. aizawai	45020116	68467	PER	
	Transgenic Corn Expressing Bacillus thuringiensis var. aizawai (B.t.) Cry1F Delta Endotoxin: A Dietary Toxicity Study with the Northern Bobwhite	45020112	68467	PER	
Signature			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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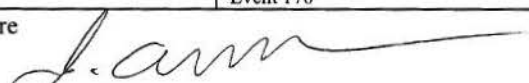


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DATA MATRIX

Date: June 11, 2008		EPA Reg. No./File Symbol: 68467-2		Page 20 of 56	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: Herculex® I Insect Protection			
Ingredient <i>B.t.</i> Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Supplement to MRID 44714801: Supplemental Data - Product Characterization Data for <i>Bacillus thuringiensis</i> var. <i>aizawai</i> Cry 1F Insect Control Protein as Expressed in Maize	45020117	68467	PER	
	High Dose Demonstration For Cry1F Events TC1360 and TC 1507: European Corn Borer	45131101	68467	PER	
	Toxicity of the Cry1F Protein to Neonate Larvae of the Monarch Butterfly	45131102	68467	PER	
	Public Interest Document for Cry1F-Protected Corn (Dow AgroSciences)	45131103	68467	PER	
	Quantitative ELISA Analysis of Cry1A(b) Expression Levels in and Composition of Hybrid Lines Derived from Event 176	45131104	68467	PER	
Signature 		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008	

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Date: June 11, 2008			EPA Reg. No./File Symbol: 68467-2	Page 21 of 56	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® I Insect Protection		
Ingredient <i>B.t.</i> Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Thermolability of Cry1F (truncated) Delta-Endotoxin	45274801	68467	PER	
	Compositional Analysis of Maize MPS Hybrid Line 1507	45274802	68467	PER	
	Cry1F Lateral Flow Test Kit Procedure for Analyzing Cry1F Corn Grain	45279301	68467	PER	
	Method Validation Report for the Determination of Cry1F Delta-endotoxin Protein in Corn Grain by Enzyme-Linked Immunosorbent Assay	45279302	68467	PER	
	Supplement to MRID 45020109: Cry1F Bacillus Thuringiensis Var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with Green Lacewing Larvae	45307801	68467	PER	
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Date: June 11, 2008		EPA Reg. No./File Symbol: 68467-2		Page 22 of 56	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: Herculex® I Insect Protection			
Ingredient <i>B.t.</i> Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Supplement to MRID 45020110: Cry1F Bacillus Thuringiensis Var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with the Ladybird Beetle	45307802	68467	PER	
	Supplement to MRID 45020111: Cry1F Bacillus Thuringiensis Var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with Parasitic Hymenoptera	45307803	68467	PER	
	Supplement to MRID 45020106: Cry1F Bacillus Thuringiensis Var. Aizawai Delta Endotoxin: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate	45307804	68467	PER	
	Supplement to MRID 45041503: Evaluation of the Dietary Effect(s) on Honeybee Development Using Bacterially Expressed Bt Cry1F Delta-Endotoxin and Pollen from Maize Expressing Bt Cry1F Delta-Endotoxin	45307805	68467	PER	
	Supplement to MRID #45131102: Supplemental Data-High Dose Demonstration for Cry1F Events TC1360 and TC1507: European Corn Borer	45307701	68467	PER	
Signature 		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008	

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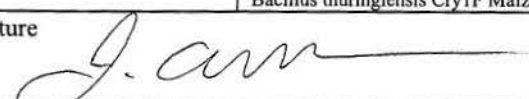


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Date: June 11, 2008		EPA Reg. No./File Symbol: 68467-2		Page 23 of 56	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: Herculex® I Insect Protection			
Ingredient B.t. Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Waiver Request: Fish Toxicity Text to Assess the Potential Effects of Maize Containing Bacillus thuringiensis var. aizawai (Bt) Cry1F Insecticidal Crystal Protein (ICP) on Native Fish	45307702	68467	PER	
	Supplement to MRID 45131103: Supplemental Data Public Interest Document for Cry 1F-Protected Corn (Dow AgroSciences L.L.C.)	45301101	68467	PER	
	Exposure and risk assessment of Herculex® I Bt field corn pollen to the Karner blue butterfly	45512901	68467	PER	
	Nutritional equivalency of B.t. Cry1F maize-poultry feed	45622001	68467	PER	
	Field Survey of Beneficial Arthropods Associated with Bacillus thuringiensis Cry1F Maize	45648001	68467	PER	
Signature 		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008	

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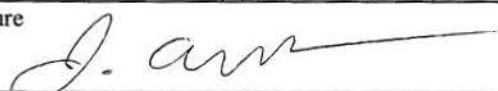


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Date: June 11, 2008		EPA Reg. No./File Symbol: 68467-2		Page 24 of 56	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: Herculex® I Insect Protection			
Ingredient <i>B.t.</i> Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Field Surveys of Non-Target Invertebrate Populations in Bt Corn	45652001	68467	PER	
	Development and Characterization of Enzyme Linked-Immunosorbent Assay (ELISA) for Detection of Cry1F Protein	45685601	68467	PER	
	Independent Laboratory Validation of Method GRM 02.13, Determination of Cry1F delta-Endotoxin Protein in Corn Grain by an Enzyme Linked Immunosorbent Assay	45685602	68467	PER	
	Supplemental to MRID 45131102: Toxicity of the Cry1F Protein to Neonate Larvae of the Monarch Butterfly	45759701	68467	PER	
	Stewardship of Herculex I (PIP) Label with Respect to the Secondary Lepidopteran Pest Western Bean Cutworm (Richia Albicosta Smith)	45885501	68467	PER	
Signature 		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008	

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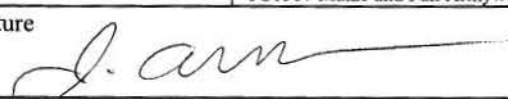


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Date: June 11, 2008		EPA Reg. No./File Symbol: 68467-2		Page 25 of 56	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: Herculex® I Insect Protection			
Ingredient <i>B.t.</i> Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Stewardship of Herculex I with respect to the secondary lepidopteran pests lesser cornstalk borer (<i>Elasmopalpus lignosellus</i> , Zeller), southern corn stalk borer (<i>Diatraea crambidoides</i> , Grote) and sugarcane borer (<i>Diatraea saccharalis</i> , Fabricius)	46600201	68467	PER	
	Slide Presentation Summarizing European Corn Borer and Cry1F Resistance Monitoring Update	46695801	68467	PER	
	Research Results on 2004 European Corn Borer Collection from Hamilton County, Iowa	47011201	68467	PER	
	Soil Accumulation of Cry1F Protein after Three Years of Cropping with Herculex	47120701	68467	PER	
	TC1507 Maize and Fall Armyworm in Puerto Rico	47176001	68467	PER	
Signature 		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008	

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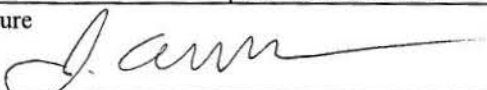
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3).

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Sidhu, R. S. (2004). Human Health and Environmental Assessment of the Plant-Incorporated Protectant <i>Bacillus thuringiensis</i> Cry3Bb1 Protein Produced in MON 88017. MSL-18835	461817-01	Monsanto Company	OWN	Product Characterization
885.1100	Beasley, K. A., H.M. Anderson., P.B. Wimberley, D.W. Mittank., and R.P. Lirette. (2002). Molecular analysis of YieldGard®Rootworm/Roundup Ready®Corn Event MON 88017. MSL-17609	461817-02	Monsanto Company	OWN	Product Characterization
885.1100	Bhakta, N. S., A. J. Hartmann, and J. C. Jennings (2003). Cry3Bb1 and CP4 EPSPS Protein Levels in Corn Tissues Collected from MON 88017 Corn Produced in U.S. Field Trials Conducted in 2002. MSL-18823	461817-03	Monsanto Company	OWN	Product Characterization
885.1100	Duan, J. J., M. S. Paradise and C. Jiang (2003). Evaluation of Functional Equivalence of Two Cry3Bb1 Protein Variants Against Susceptible Coleopteran species. MSL-18799	461817-04	Monsanto Company	OWN	Product Characterization
885.1100	Hileman, R. E. and J. D. Astwood (2001). Additional Characterization of the Cry3Bb1 Protein Produced in MON 863. MSL-17137	454240-10	Monsanto Company	OWN	Product Characterization
Signature			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Hileman, R. E., G. Holleschak, L. A. Turner, R. S. Thoma, C. R. Brown and J. D. Astwood (2001). Characterization and Equivalence of the Cry3Bb1 Protein Produced by <i>E. coli</i> Fermentation and MON 863. MSL-17274	455382-01	Monsanto Company	OWN	Product Characterization
860.1340	Brown, M. (2003). <i>TraitChek</i> ™ Cry3Bb Lateral Flow Test Strip and <i>SeedChek</i> ™ Cry3Bb ELISA Performance Verification for Corn Seed, Leaf, and Composite Testing. MSL-19581, in unpublished study conducted by Strategics Diagnostics, Inc.	463942-01	Monsanto Company	OWN	Product Characterization
885.1100	Dudin, Y. A., B-P. Tonnu, L. D. Albee and R. P. Lirette (2001). Amended Report for MSL-16559: <i>B.t.</i> Cry3Bb1.11098 and NPTII Protein Levels in Sample Tissue Collected from MON 863 Grown in 1999 Field Trials. MSL-17181	454240-01	Monsanto Company	OWN	Product Characterization
885.1100	Supplemental Information for "Evaluation of Functional Equivalence of Two Cry3Bb1 Protein Variants Against Susceptible Coleopteran Species" (MRID No. 461817-04)	465783-03	Monsanto Company	OWN	Product Characterization
885.1100	Thoma, R. S., G. Holleschak, R. E. Hileman and J. D. Astwood (2001). Primary Structural Protein Characterization of MON 863 Cry3Bb1.11098 Protein Using N-terminal Sequencing and MALDI Time-of-Flight Mass Spectrometric Techniques. MSL-17154	454240-11	Monsanto Company	OWN	Product Characterization
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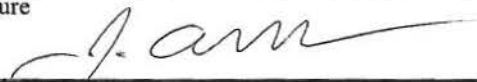
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Submission of Supplemental Data (May 21, 2001) in Support of the Application for Registration of MON 863: Corn Rootworm Protected Corn (Vector ZMIR13L); EPA File Symbol 524-LEL.	N/A	Monsanto Company	OWN	Product Characterization
885.1100	Dudin, Y., B-P. Tonnu and R. P. Lirette (2001). Cry3Bb1, Cry1Ab and NPTII Protein Levels in the Dual-trait Maize Hybrid MON 863 x MON 810 Produced in Argentinian Field Trials Conducted During the 1999-2000 Growing Season. MSL-17266	457917-02	Monsanto Company	OWN	Product Characterization
885.1100	Holleschak, G., T. C. Lee, R. E. Hileman, P. D. Pyla, and J. D. Astwood (2001). Amended Report for MSL-15835: Assessment of the Equivalence of <i>B.t.</i> Protein 11098, <i>B.t.</i> Protein 11231 and NPTII Protein Expressed in Corn Events MON 853 and MON 860 to Microbial Sources. MSL-17222	454240-04	Monsanto Company	OWN	Product Characterization
885.1100	Supplemental Information for "Cry3Bb1 and CP4 EPSPS Protein Levels in Corn Tissues Collected from MON 88017 Corn Produced in U.S. Field Trials Conducted in 2002" (MRID No. 461817-03)	465783-02	Monsanto Company	OWN	Product Characterization
885.1100	Holleschak, G., R. E. Hileman, and J. D. Astwood (2001). Amended Report for MSL-16596: Assessment of the Physicochemical Equivalence of Cry3Bb1.11098 and NPTII Proteins in Corn Event MON 863 to Microbial Sources. MSL-17220	454240-05	Monsanto Company	OWN	Product Characterization
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Supplemental Information for "Molecular Analysis of YieldGard® Rootworm/Roundup Ready® Corn Event MON 88017" (MRID No. 461817-02)	465783-01	Monsanto Company	OWN	Product Characterization
860.1340	D. Kolwyck, B-P. Tonnu, Y. A. Dudin, T. Ploesser and K. Gustafson (2001). Validated Method for Extraction and Direct ELISA Analysis of Cry3Bb1 in Corn Grain. Monsanto Ref. No. 99-640E-1.	453731-01	Monsanto Company	OWN	Product Characterization
N/A	Astwood, J. D., R. E. Hileman, M. J. McKee, T. J. Rydel, J. W. Seale and L. English (2001). Safety Assessment of Cry3Bb1 Variants in Corn Rootworm Protected Corn. MSL-17225	454240-09	Monsanto Company	OWN	Human Health Assessment
885.1100	Hileman, R. E., J. N. Leach and J. D. Astwood (2001). Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1.11098(Q349R) Protein in Simulated Intestinal Fluid. MSL-17530	455770-02	Monsanto Company	OWN	Human Health Assessment
885.1100	Holleshak, G., R. E. Hileman and J. D. Astwood (2001). Amended Report for MSL-16597: Immunodetectability of Cry3Bb1.11098 and Cry3Bb1.11231 Proteins in the Grain of Insect Protected Corn Events MON 863 and MON 855 After Heat Treatment. MSL-17223	454240-07	Monsanto Company	OWN	Human Health Assessment

Signature

Name and Title

J. Austin Burns, Ph.D.
Regulatory Affairs Manager

Date

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 88017			
Ingredient <i>B.t.</i> Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.3050	Bechtel, C. L. (1999). Acute Oral Toxicity of <i>B.t.</i> Protein 11231 in Mice. MSL-16216.	449043-05	Monsanto Company	OWN	Human Health Assessment
885.1100	Hileman, R. E., E. A. Rice, R. E. Goodman and J. D. Astwood (2001). Bioinformatics Evaluation of the Cry3Bb1 Protein Produced in MON 863 Utilizing Allergen, Toxin and Public Domain Protein Databases. MSL-17140	454240-08	Monsanto Company	OWN	Human Health Assessment
885.3050	Bonnette, K. L. and P. D. Pyla (2001). An Acute Oral Toxicity Study in Mice with <i>E. coli</i> Produced Cry3Bb1.11098(Q349R) Protein, Amended Final Report. MSL-17382	455382-02	Monsanto Company	OWN	Human Health Assessment
885.1100	Leach, J. N., R. E. Hileman and J. D. Astwood (2001). Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1 Protein Purified from MON 863 and Cry3Bb1 Protein Purified from <i>E. coli</i> . MSL-17292	455382-03	Monsanto Company	OWN	Human Health Assessment
885.3050	Bechtel, C. L. (1999). Acute Oral toxicity of <i>B.t.</i> Protein 11098 in Mice. MSL-16215	449043-06	Monsanto Company	OWN	Human Health Assessment
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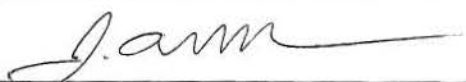
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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Hileman, R. E. and J. D. Astwood (1999). Bioinformatics Analysis of <i>B.t.</i> Protein 11098 and <i>B.t.</i> Protein 11231 Sequences Utilizing Toxin and Public Domain Genetic Databases. MSL-15870	449043-08	Monsanto Company	OWN	Human Health Assessment
885.1100	Hileman, R. E. and J. D. Astwood (1999). Bioinformatics Analysis of <i>B.t.</i> Protein 11098 and <i>B.t.</i> Protein 11231 Sequences Utilizing an Allergen Database. MSL-15873	449043-09	Monsanto Company	OWN	Human Health Assessment
885.1100	Leach, J. N., R. E. Hileman, J. W. Martin, R. S. Thoma, and J. D. Astwood (2001). Amended Report for MSL-15704: Assessment of the <i>In Vitro</i> Digestibility of <i>B.t.</i> protein 11098 and <i>B.t.</i> 11231 Utilizing Mammalian Digestive Fate Models. MSL-17166	454240-06	Monsanto Company	OWN	Human Health Assessment
885.4200	McKee, M. J. (2001). Bluegill Dietary Toxicity Study for the <i>Bacillus thuringiensis</i> Cry3Bb1 Protein Variant: A Waiver Request. MSL-17383	455382-00	Monsanto Company	OWN	Environmental Assessment
885.4240 Series 72, Subdivision E	Drott, K. R. and H. O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11098 in Corn Pollen: 48-Hour Static Renewal Acute Toxicity Test with the Cladoceran (<i>Daphnia magna</i>). MSL-16163	449043-18	Monsanto Company	OWN	Environmental Assessment
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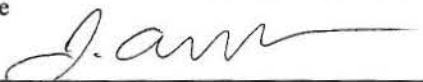
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t. Cry3Bb1* protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4280	Results of acute toxicity tests with <i>Daphnia</i> and catfish did not produce any evidence of adverse effects. Estuarine and Marine animal studies are waived for this product because of the very low to no potential for exposure to Cry3Bb1 protein from field corn.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
885.4340	Texiera, D. (2005). Evaluation of Dietary Effects of a Cry3Bb1 Protein Variant on Minute Pirate Bugs (<i>Orius insidiosus</i>). MSL-19697	464799-05	Monsanto Company	OWN	Environmental Assessment
885.4300	Since the active ingredient in this product is an insect toxin (Bt endotoxin) that has never shown any toxicity to aquatic or terrestrial plants, these studies have been waived for this product. The Agency has determined there is no significant risk of gene capture and expression of Cry3Bb1 protein by wild or weedy relatives of corn.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
885.4340	Palmer, S. J. and H. O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: Dietary Toxicity Study with the Ladybird Beetle (<i>Hippodamia convergens</i>). MSL-16166	449043-14	Monsanto Company	OWN	Environmental Assessment
850.6200	Hoxter, K. A., S. J. Palmer and H. O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: An Acute Toxicity Study with Earthworm in an Artificial Soil Substrate. MSL-16162	449043-16	Monsanto Company	OWN	Environmental Assessment
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Teixeira, D. (1999). Assessment of Chronic Toxicity of Corn Tissue Containing the <i>Bacillus thuringiensis</i> Protein 11098 to Collembola (<i>Folsomia candida</i>). MSL-15988	449043-17	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S. J. and H. O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: A Dietary Study with Green Lacewing Larvae (<i>Chrysoperla carnea</i>). MSL-16165	449043-12	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S. J. and H. O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: A Dietary Study with the Parasitic Hymenoptera (<i>Nasonia vitripennis</i>). MSL-16167	449043-13	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman, S., M. Bhatti, B. Ayden, J. Murphy, S. Levine and C. Jiang (2005). Environmental Fate of Cry3Bb1 Protein in Corn Fields Planted with MON 863. MSL-19285	465103-01	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan, J. J., G. Head, M. McKee and T. E. Nickson (2001). Dietary Effects of Transgenic <i>Bacillus thuringiensis</i> (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Adults of the Ladybird Beetle, <i>Coleomegilla maculata</i> . MSL-16936	453613-01	Monsanto Company	OWN	Environmental Assessment
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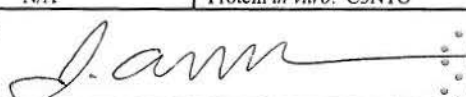
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t. Cry3Bb1* protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Bryan, R. L., J. R. Porch and H. O. Krueger (2001). Dietary Effects of Transgenic BT Corn Pollen Expressing a Variant of Cry3Bb1 Protein on the Ladybird Beetle, <i>Hippodamia convergens</i> . MSL-17171	453613-02	Monsanto Company	OWN	Environmental Assessment
154-3500	Bhatti, M. A., C. L. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. D. Pilcher (2001). Field Evaluation for the Ecological Impact of Corn Rootworm Insect-Protected Corn on Non-Target Organisms. MSL-17179	455382-06	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan, J. J., M. J. McKee and T. E. Nickson (2001). Dietary Effects of Transgenic <i>Bacillus thuringiensis</i> (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Larvae of the Ladybird Beetle, <i>Coleomegilla maculata</i> . MSL-16907	455382-04	Monsanto Company	OWN	Environmental Assessment
885.4340	Sears, M. and M. Mattila (2002). Determination of the Toxicity of Corn Pollen Expressing a Cry3Bb1 Variant Protein to First Instar Monarch Butterfly Larvae (<i>Danux plexippus</i>) via Laboratory Bioassay. MSL-17235	455382-05	Monsanto Company	OWN	Environmental Assessment
N/A	Head, G., M. Pleau, S. Sivausupramanian and T. Vaughn (2001). Insecticidal Spectrum of Activity for Cry3Bb1 Protein <i>in vitro</i> . C3NTO	455382-07	Monsanto Company	OWN	Environmental Assessment
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Duan, J. J., M. J. McKee, G. Head and C. R. Brown (2002). Endangered Species Impact Assessment for Cry3Bb1 Protein in Transgenic MON 863. MSL-17614	455770-03	Monsanto Company	OWN	Environmental Assessment
154-2300	Head, G. (2002). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Results. Monsanto Reference No. 00-CR-032E-7	456530-03	Monsanto Company	OWN	Environmental Assessment
154-3500	Bhatti, M. A., J. D. Duan, C. L. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. Jiang (2002). Ecological Assessment of Nontarget Organisms in the Plots of Corn Rootworm Insect Protected Corn Hybrid Containing MON 863 Event: 2000 - 2001 Field Trials. Report MSL-17531	457916-01	Monsanto Company	OWN	Environmental Assessment
850.6200	Sindermann, A. B., J. R. Porsch and H. O. Krueger (2002). Evaluation of a Cry3Bb1 Protein Variant in an Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. MSL-18137	457571-01	Monsanto Company	OWN	Environmental Assessment
885.4050	Gallagher, S. P., J. Grimes and J. B. Beavers (1999). <i>Bacillus thuringiensis</i> Protein 11231 in Corn Grain: A Dietary Toxicity Study with the Northern Bobwhite. MSL-16161	449043-15	Monsanto Company	OWN	Environmental Assessment
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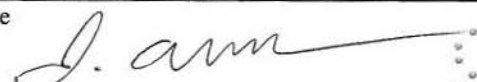
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Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4380	Maggi, V. L. (1999). Evaluation of the Dietary Effect(s) of Purified <i>Bacillus thuringiensis</i> Protein 11231 on Adult Honey Bees (<i>Apis mellifera</i> L.). MSL-16169	449043-11	Monsanto Company	OWN	Environmental Assessment
885.5200	Martin, J. W., M. J. McKee, S. Dubelman and Y. A. Dudin (2000). Aerobic Soil Degradation of the <i>B.t.</i> Protein 11098 as a Component of Insect Protected Corn. MSL-16440	451568-04	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman, S., B. Ayden, M. Mueth, J. A. Warren, C. Jiang, J. Bookout and Y. Dudin (2002). Aerobic Soil Degradation of the <i>Bacillus thuringiensis</i> Cry3Bb1 Variant Protein Produced in Corn Rootworm Protected MON 863. MSL-17102	457571-02	Monsanto Company	OWN	Environmental Assessment
885.4050	George, B. (2001). Comparison of Broiler Performance When Fed Diets Containing Events MON 863, Parental Line or Commercial Corn. MSL-17243	459415-01	Monsanto Company	OWN	Environmental Assessment
885.4380	Maggi, V.L. (1999). Evaluation of the Dietary Effects of Purified <i>Bacillus thuringiensis</i> Protein 11231 on Honey Bee Larvae. MSL-16168	449043-10	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman, S., B. Ayden, J. Colyer, B. Ledesma, S. Levine, F. Lloyd, G. Mueller, J. Warren & C. Jiang (2007). Environmental Fate of the Cry3Bb1 and Cry1Ab Proteins in Corn Fields Planted with MON 863 x MON 810 for Three Consecutive Years MSL-20589	472829-02	Monsanto Company	OWN	Environmental Assessment
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-3500	Duan, J., M. Bhatti, C. Brown, G. Head, C. Jiang, C. Pilcher, C. Pilcher, D. Carson & T. Nickson (2007) Two Year Field Assessment of the Effect of Combined Trait Bt Corn Mon 863 x MON 810. MSL-19696	472829-01	Monsanto Company	OWN	Environmental Assessment
154-3500	Duan J. J., C. Jiang, M.J. McKee, M.A. Nemeth, D. Ward, G. Head, S. Levine, M. Bhatti and M. Paradise (2004). Statistical Power Analysis of a Two-Year Field Study Evaluating the Ecological Effect of Corn Event MON 863. MSL-19246	462627-03	Monsanto Company	OWN	Environmental Assessment
154-3500	Duan J. J., C. Jiang, C. Brown, M. Bhatti, M. Nemeth, T. Nickson and D. Ward (2004). Supplemental Statistical Analysis of Data from a Two-Year Field Census Study with Corn Event MON 863. MSL-19329	463942-02	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman S., M. Bhatti and B. Ayden (2004). Interim Report: Assessment of the Environmental Fate of the Cry3Bb1 Protein in Corn Fields Planted with MON 863. MSL-18931	462001-01	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan J. and M. Paradise (2005). Evaluation of Dietary Effects of Cry3Bb1 Protein on the Ground Beetle <i>Poecilus chalcites</i> (Coleoptera:Carabidae). MSL-19631	464799-04	Monsanto Company	OWN	Environmental Assessment
154-3500	Head, G. (2004). Research on the Effects of Corn Rootworm Protected Transgenic Corn on Non-Target Organisms: Publications & Manuscripts.	462627-02	Monsanto Company	OWN	Environmental Assessment

Signature

Name and Title

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Regulatory Affairs Manager

Date

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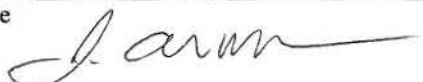


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Date: June 11, 2008			EPA Reg. No./File Symbol: 524-551		Page 38 of 56
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 88017		
Ingredient <i>B.t.</i> Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4150	Mammalian wildlife exposure to Cry3Bb1 protein is considered likely; however, the Cry3Bb1 toxicity data for Human Health Assessment indicate that there is no significant toxicity to rodents from testing at the maximum hazard dose. Therefore no hazard to mammalian wildlife is anticipated.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
885.4200	Li, M. H. and E. H. Robinson (1999). Evaluation of Insect Protected Corn Lines MON 853 and MON 859 as a Feed Ingredient for Catfish. MSL-16164	449043-19	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan, J. J., G. Head, M. J. McKee and D. P. Ward (2003). Data Waiver Request: Toxicity of <i>B.t.</i> Cry3Bb1 Protein in the Red Milkweed Beetle (<i>Tetraopes</i> sp.). MSI-18741	N/A	Monsanto Company	OWN	Environmental Assessment Granted in BRAD
N/A	Pilcher, C. D. (2001). Efficacy of MON 863 Against Corn Rootworm and Comparison to Insecticide Treatments - Results of Year 2000 Field Trials. Monsanto Ref. No. 00-CR-032E-3	453613-03	Monsanto Company	OWN	Benefits
N/A	Mitchell, P. D. (2002). Yield Benefit of MON 863. MSL-17782	456530-02	Monsanto Company	OWN	Benefits
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Ward, D. P. (2002). Public Interest Assessment Supporting Registration of <i>Bacillus thuringiensis</i> Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in MON 863. MSL-17766	456530-01	Monsanto Company	OWN	Benefits
N/A	Miller, D. (2000). Public Interest Document Supporting the Registration and Exemption from the Requirement of a Tolerance for the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry3Bb Protein, and the Genetic Material Necessary for its Production in Corn (Vectors ZMIR12L, ZMIR13L and ZMIR14L). Monsanto Ref. No. 99-781E	450297-01	Monsanto Company	OWN	Benefits
N/A	Alston, J. M., J. Hyde and M. C. Marra (2002). An Ex Ante Analysis of the Benefits from the Adoption of Monsanto's Corn Rootworm Resistant Varietal Technology - YieldGard® Rootworm. MSL-17993	456923-01	Monsanto Company	OWN	Benefits
N/A	Vaughn, T. T., M. Pleau, R. Knutson and T. Coombe (2001). Comparing the Efficacy of MON 853 and MON 863 to Three Corn Rootworm Species, Northern Corn Rootworm (<i>Diabrotica barberi</i>), Southern Corn Rootworm (<i>D. undecimpunctata howardi</i>), and Western Corn Rootworm (<i>D. virgifera virgifera</i>). MTC RPT4	455382-08	Monsanto Company	OWN	Benefits
N/A	Vaughn, T., D. Ward, J. Pershing, G. Hez and J. McFerson (2001). An Interim Insect Resistance Management Plan for MON 863: A Transgenic Corn Rootworm Control Product. MSL-17556	455770-01	Monsanto Company	OWN	Benefits/IRM
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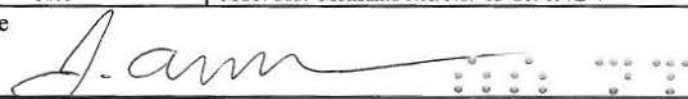
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	T. Vaughn (2004). Progress Report on Insect Resistance Management for Corn Event MON 863.	461865-01	Monsanto Company	OWN	IRM
N/A	Vaughn, T. (2001). Preliminary Results of Research on Insect Resistance Management for a Transgenic Corn Rootworm Control Product.	453484-01	Monsanto Company	OWN	IRM
N/A	Head, G. and K. Reding. (2006). Corn rootworm Insect Resistance Management Research (fourteen journal publications)	467424-01	Monsanto Company	OWN	IRM
N/A	Davis, P., G. Head, J. McFerson et. al. (2000). Insect Resistance Management for a Transgenic Corn Rootworm Control Product.	451568-05	Monsanto Company	OWN	IRM
N/A	Vaughn, T. (2003). Estimating Cry3Bb1 Resistance Allele Frequencies in Corn Rootworm Larvae Feeding on MON 863. Monsanto Ref. No. 03-CR-097E-4	459438-01	Monsanto Company	OWN	IRM
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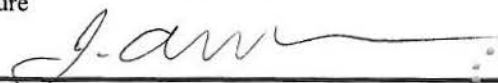
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	T. Vaughn (2005). Second Progress Report on Insect Resistance Management for Corn Event MON 863. REVISED	N/A	Monsanto Company	OWN	IRM
N/A	Letter submitted May 23, 2003 to EPA with 12 research protocols on the biology and ecology of the corn rootworm pest complex.	N/A	Monsanto Company	OWN	IRM
N/A	Vaughn, T. (2004). 2004 Progress Report for the Corn Event MON 863 Resistance Monitoring Program.	462627-01	Monsanto Company	OWN	IRM
N/A	Administrative Materials in Support of the Registration of <i>Bacillus thuringiensis</i> Cry3Bb Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn; and Amendment of the Previous Request for Exemption from the Requirement of a Tolerance, PP7F4888	451568-00	Monsanto Company	OWN	Tolerance Exemption
N/A	Pilacinski, W. P. and M. W. Taylor (1999). Administrative Materials in Support of the Registration of the Plant-Expressed Protectant <i>Bacillus thuringiensis</i> Corn Rootworm Control Protein, as Produced in the Corn (<i>Zea mays</i> , L.), and the Amendment to the Previous Request for Exemption from the Requirement of a Tolerance, PP7F4888	449043-00	Monsanto Company	OWN	Tolerance Exemption
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Petition for Exemption from the Requirement of a Tolerance for <i>Bacillus thuringiensis</i> Cry1, Cry2, and Cry3 Classes of Proteins and the Genetic Material Necessary for the Production of These Proteins In or On All Raw Agricultural Commodities When used as Plant-Pesticide Active Ingredients.	PP 7F4888	Monsanto Company	OWN	Tolerance Exemption
885.1100	McCoy, R. L. and A. Sivanovich (2003). Bioinformatics Analysis of the CP4 EPSPS Protein Utilizing the AD4, TOXINS and ALLPEPTIDES Databases. MSL18752	466361-01	Monsanto Company	OWN	Inert Ingredient
885.1100	McCoy, R.L. and A. Sivanovich (2005). Updated Bioinformatics Evaluation of the CP4 EPSPS Protein Utilizing the AD5 Database. MSL19894	466361-02	Monsanto Company	OWN	Inert Ingredient
885.3050	Monsanto Company (1995). Submission of Toxicology Data in Support of a Tolerance Petition for CP4 EPSPS as a Plant Pesticide Formulation Inert Ingredient. Transmittal of 1 Study.	436919-00	Monsanto Company	OWN	Inert Ingredient
885.3050	Harrison, L., M. Bailey, D. Nida, M. Taylor, L. Holden and S. Padgett (1993). Preparation and Confirmation of Doses for an Acute Mouse Feeding Study With CP4 EPSPS. Lab Project Numbers: 92-01-30-12; 92-01-30-19	436919-01	Monsanto Company	OWN	Inert Ingredient
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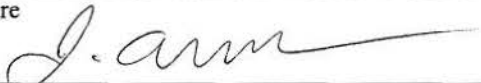
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t. Cry3Bb1* protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Padgett, S., G. Barry, D. Re, D. Eichholtz, M. Weldon, K. Kolacz and G. Kishore (1993). Purification, Cloning, and Characterization of a Highly Glyphosate-Tolerant 5-Enolpyruvylshikimate-3-phosphate Synthase from <i>Agrobacterium sp.</i> Strain CP4. MSL-12738	438076-01	Monsanto Company	OWN	Inert Ingredient
885.1100	Bishop, B. (1993). Production of CP4 EPSP in a 100 Liter Recombinant <i>Escherichia coli</i> Fermentation. MSL-12389	438076-02	Monsanto Company	OWN	Inert Ingredient
885.1100	Heeren, R., S. Padgett and M. Gustafson (1993). The Purification of Recombinant <i>Escherichia coli</i> CP4 5-enolpyruval-shikimate-3-phosphate synthase for Equivalence Studies. MSL-12574	438076-03	Monsanto Company	OWN	Inert Ingredient
N/A	Monsanto Company (1995). Submission of Product Chemistry, Toxicology and Pesticide Fate in Animals Data in Support of the Exemption for the Requirement of a Petition for Tolerance for CP4 EPSPS. Transmittal of 4 studies.	436433-00	Monsanto Company	OWN	Inert Ingredient
885.1100	Harrison, L., M. Bailey, R. Leimgruber, C. Smith, D. Nida, M. Taylor, M. Gustafson, B. Heeren and S. Padgett (1993). Characterization of Microbially-Expressed Protein: CP4 EPSPS. Lab Project Number: 92/01/30/14. 12901	436433-01	Monsanto Company	OWN	Inert Ingredient
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Lee, T., M. Bailey, C. Smith, J. Zeng, E. Elswick and P. Sanders (1995). Assessment of the Equivalence of CP4 EPSPS Protein Produced in <i>Escherichia coli</i> and European Corn Borer Resistant Corn. Lab Project Number: 94-01-39-10: MSL-13920	436433-02	Monsanto Company	OWN	Inert Ingredient
885.3050	Naylor, M. (1993). Acute Oral Toxicity Study of CP4 EPSPS in Albino Mice. Lab Project Number: 92223	436433-03	Monsanto Company	OWN	Inert Ingredient
885.1100	Ream, J., M. Bailey, J. Leach and S. Padgett (1993). Assessment of the in vitro Digestive Fate of CP4 EPSPS Synthase. Lab Project Number: 92-01-30-15: 12949	436433-04	Monsanto Company	OWN	Inert Ingredient
N/A	Revisions and Clarification to the Terms & Conditions of Registration for Corn Event MON 863 and YieldGard® Plus Corn; Progress Report on Multiple IRM-Related Activities for MON 863; and Response to EPA Letter Dated August 13, 2004. Submitted 7/7/2005.	N/A	Monsanto Company	OWN	Terms & Conditions
N/A	Siegfried, B. and T. Spencer (2000). Susceptibility of Neonate Rootworm Larvae to the Cry3Bb1 Toxin from <i>Bacillus thuringiensis</i> . This report satisfies the insect Monitoring Terms & Conditions.	467259-01	Monsanto Company	OWN	Terms & Conditions
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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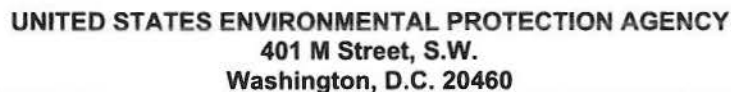
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® RW Insect Protection		
Ingredient <i>B.t.</i> Cry34/35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Phosphinothricin acetyltransferase (PAT) protein: In Vitro Digestibility Study	45041501	64867	PER	
	PS149B1 Binary Insecticidal Crystal Protein: Acute Toxicity to the Earthworm in an Artificial Substrate	45360201	68467	PER	
	Microbial PS149B1 Binary Delta-Endotoxin: Maize-Insect-Pest Susceptibility Study	45242204	68467	PER	
	Comparison of the Amino Acid Sequence of the <i>Bacillus thuringiensis</i> Strain PS149B1 13.6 kDa and 43.8 kDa Insecticidal Crystal Proteins to Known Protein Allergens	45242205	68467	PER	
	PS149B1 14 KDA Protein: Acute Oral Toxicity Study in CD-1 Mice	45242207	68467	PER	
	PS149B1 44 KDA Protein: Acute Oral Toxicity Study in CD-1 Mice	45242208	68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008

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Date: June 11, 2008	EPA Reg. No./File Symbol: 68467-5	Page 46 of 56
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® RW <i>Insect Protection</i>	
Ingredient <i>B.t.</i> Cry34/35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)		

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Date: June 11, 2008

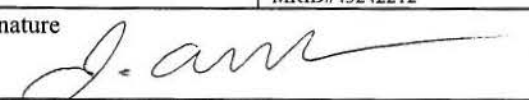
EPA Reg. No./File Symbol: 68467-5

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW *Insect Protection*Ingredient *B.t. Cry34/35Ab1* Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	PS149B1 Binary Insecticidal Crystal Protein: An 8-Day Dietary Study with the Rainbow Trout, <i>Oncorhynchus mykiss</i> , Walbaum	45790403	68467	PER	
	PS149B1 Binary Insecticidal Crystal Protein: An Acute Toxicity Study with the Daphnid, <i>Daphnia magna</i> Straus	45790404	68467	PER	
	PS149B1 Binary Insecticidal Crystal Protein: Dietary Toxicity to Parasitic Hymenoptera (<i>Nasonia vitripennis</i>)	45790405	68467	PER	
	PS149B1 Insecticidal Crystal Protein: Dietary Toxicity to Green Lacewing Larvae (<i>Chrysoperla carnea</i>)	45790407	68467	PER	
	SDS-PAGE Sensitivity Analysis for Cry35Ab1 in Support of the Simulated Gastric Fluid Digestion Study MRID#45242212	45790408	68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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Date: June 11, 2008

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient *B.t.* Cry34/35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Trait Durability and Experimental Use of Transgenic Maize Expressing the Insecticidal Crystalline Proteins Cry34Ab1 and Cry35Ab1	45790409	68467	PER	
	Degradation of Microbial Binary PS149B1 Delta-Endotoxin in a Representative Soil from the Mid-Western USA Maize-Growing Region	45242214	68467	PER	
	Characterization of DNA Inserted into Transgenic Corn Events E4497.42.1.34, E4497.45.2.16, E4497.59.1.10, E4497.66.1.27, E4497.71.1.29 and E4497.71.1.33	45790402	68467	PER	
	Field Efficacy of Cry34Ab1/Cry35Ab1 Maize Events Against Corn Rootworms	45790410	68467	PER	
	Summary of Heat Lability Studies with Cry34Ab1/Cry35Ab1	45808601	68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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Date: June 11, 2008			EPA Reg. No./File Symbol: 68467-5		Page 51 of 56
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® RW Insect Protection		
Ingredient <i>B.t.</i> Cry34/35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	. Biological equivalency of Cry34/35Ab1 insecticidal crystal protein in transgenic plants and derived from transgenic <i>Pseudomonas fluorescens</i>	46123905	68467	PER	
	Characterization of Cry34Ab1 and Cry35Ab1 Proteins Derived from Transgenic Maize event E4497.59.1.22 (DAS-59122-7)	46123906	68467	PER	
	Characterization of Phosphinothricin Acetyltransferase (PAT) Derived from Transgenic Maize Event E4497.59.1.22	46123907	68467	PER	
	Characterization of DNA Inserted into Transgenic Corn Events DAS45216-6 and DAS-59122-7	46123908	68467	PER	
	Detailed characterization of DNA inserted into transgenic corn events DAS-45216-6 and DAS-59122-7	46123909	68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient *B.t.* Cry34/35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Investigations into Dose of Cry34Ab1/Cry35Ab1 Rootworm-Resistant Maize Event DAS-59122-7 Against Western and northern Corn Rootworms in Support of Trait Durability Plans	46123915	68467	PER	
	Effect on Western Corn Rootworm Adults of Feeding on Cry34/35Ab1-Corn Rootworm Protected Corn Tissue and Implications for Product Durability	46123916	68467	PER	
	Evaluation of endangered/threatened insect species relative to the use of Cry34Ab/Cry35Ab1 corn rootworm-resistant maize hybrids	46123917	68467	PER	
	Trait Durability Plan for Cry34/35-Corn Rootworm Protected corn Event DAS-59122-7 Following Commercialization	46123918	68467	PER	
	Simulations of Corn Rootworm Adaptation to Cry34/35-Corn Rootworm Protected Corn in Support of Trait Durability Plans for Event DAS-59122-7	46123919	68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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Date: June 11, 2008		EPA Reg. No./File Symbol: 524-XXX		Page 1 of 56	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7			
Ingredient <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034-3 × DAS- 01507 × MON- 88017-3× DAS-59122-7)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	Product Characterization This Application
			Monsanto Company	OWN	Product Characterization This Application
			Monsanto Company	OWN	Product Characterization This Application
			Monsanto Company	OWN	Product Characterization This Application
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008

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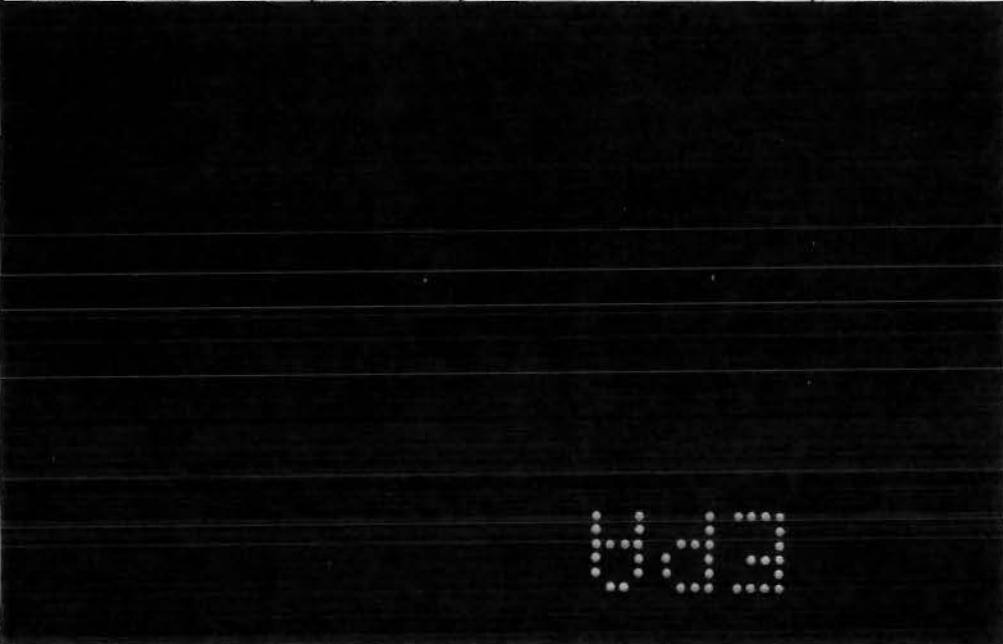
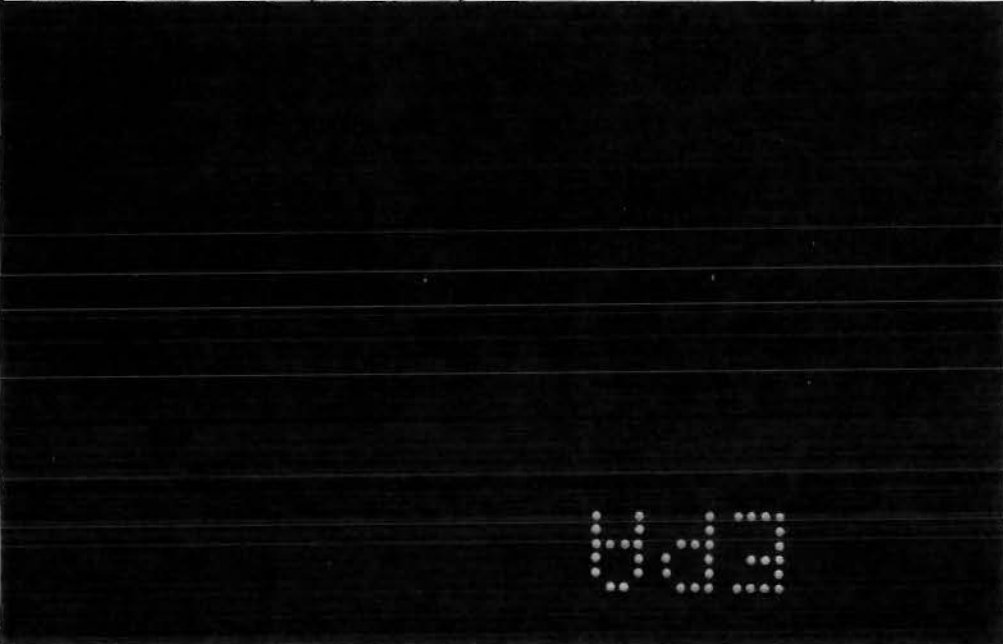
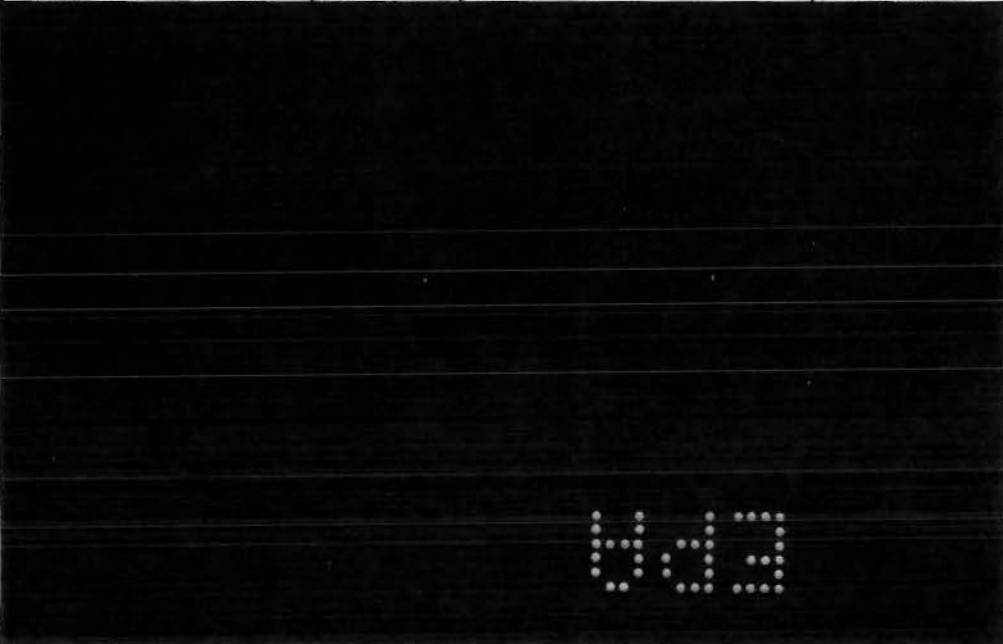

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Date: June 11, 2008	EPA Reg. No./File Symbol: 524-XXX	Page 2 of 56
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034-3 × DAS- 01507 × MON- 88017-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Product Characterization This Application
			Monsanto Company	OWN	Product Characterization This Application
			Monsanto Company	OWN	Product Characterization This Application
			Monsanto Company	OWN	Product Characterization This Application
			Monsanto Company	OWN	Product Characterization This Application
			Monsanto Company	OWN	Environmental Assessment This Application
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 × TC1507 × MON 88017 ×
DAS-59122-7

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034-3 × DAS-01507 × MON- 88017-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment This Application
			Monsanto Company	OWN	Environmental Assessment This Application
			Monsanto Company	OWN	IRM This Application
			Monsanto Company	OWN	Environmental Assessment This Application
			Monsanto Company	OWN	Environmental Assessment This Application
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
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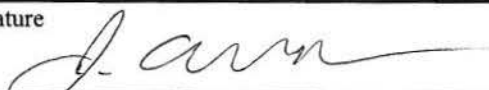
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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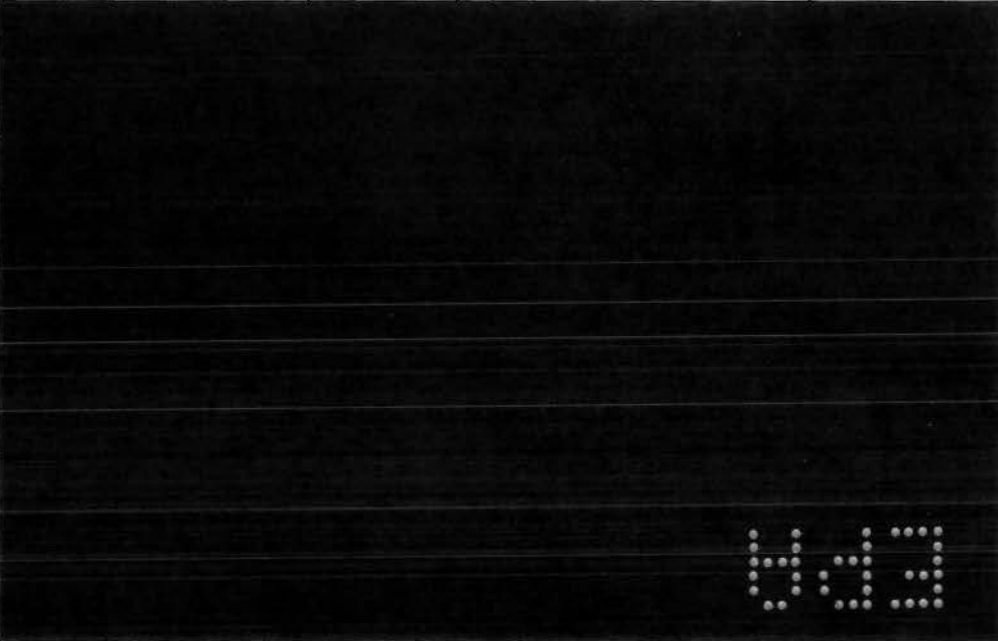




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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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Date: June 11, 2008		EPA Reg. No./File Symbol: 524-575		Page 7 of 56	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034			
Ingredient <i>Bacillus thuringiensis</i> Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034
Ingredient <i>Bacillus thuringiensis</i> Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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Date: June 11, 2008

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* CryIA.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment

Signature

Name and Title
J. Austin Burns, Ph.D.
Regulatory Affairs Manager

Date
June 11, 2008

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Date: June 11, 2008

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
Signature			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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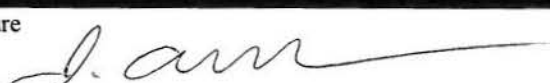
Page 11 of 56

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
Signature			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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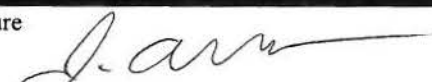

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	Benefits
			Monsanto Company	OWN	Misc.
			Monsanto Company	OWN	Misc.
			Monsanto Company	OWN	Misc.
			Monsanto Company	OWN	Misc.
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Date: June 11, 2008

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient *B.t. Cry1F* protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	

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Date
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DATA MATRIX

Date: June 11, 2008

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	

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Name and Title
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: Herculex® I Insect Protection			
Ingredient <i>B.t.</i> Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
Signature 			68467	PER	
		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008	

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Date: June 11, 2008			EPA Reg. No./File Symbol: 68467-2		Page 17 of 56
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® I Insect Protection		
Ingredient B.t. Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008

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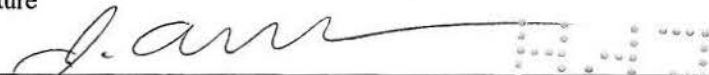


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Date: June 11, 2008			EPA Reg. No./File Symbol: 68467-2		Page 18 of 56
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® I Insect Protection		
Ingredient <i>B.t.</i> Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient *B.t. Cry1F* protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	

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Name and Title
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Regulatory Affairs Manager

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	

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Name and Title
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Regulatory Affairs Manager

Date

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient *B.t. Cry1F* protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	

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Regulatory Affairs Manager

Date

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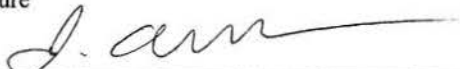
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient *B.t. Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)*

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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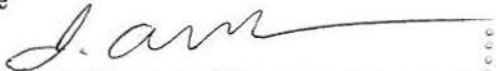
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient *B.t. Cry1F* protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15 Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
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			68467	PER	
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Date: June 11, 2008

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008

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Date: June 11, 2008

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization

Signature

Name and Title
J. Austin Burns, Ph.D.
Regulatory Affairs ManagerDate
June 11, 2008

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Date: June 11, 2008			EPA Reg. No./File Symbol: 524-551		Page 29 of 56
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 88017		
Ingredient <i>B.t.</i> Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008

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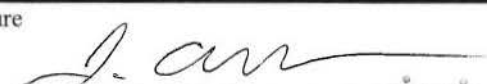
Page 30 of 56

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
Signature			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
Signature			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment Waived in BRAD
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment Waived in BRAD
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
Signature			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
Signature			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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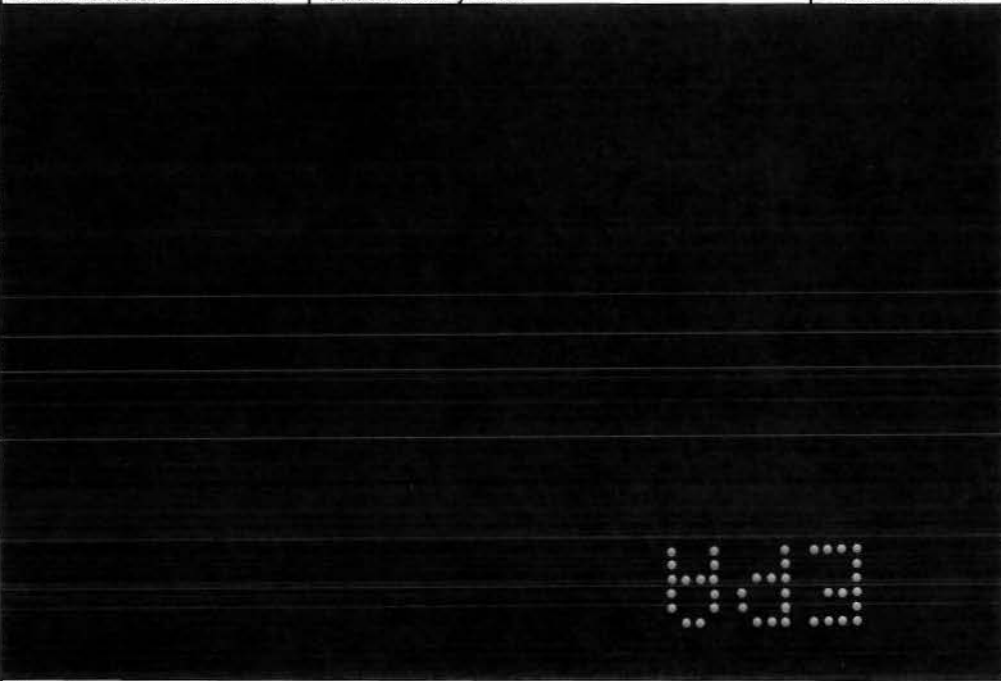
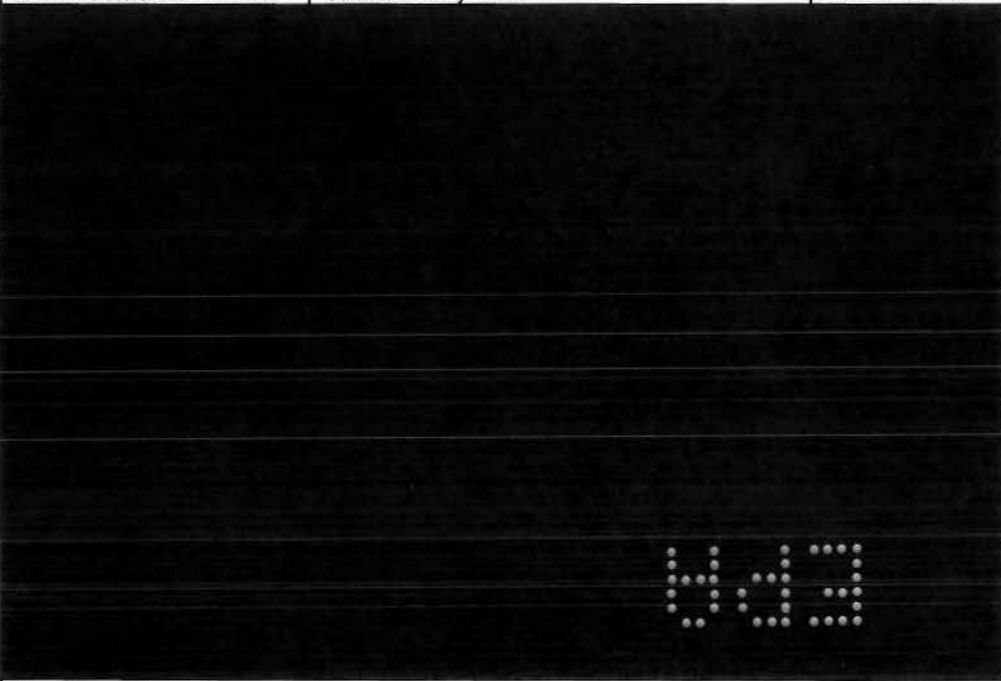
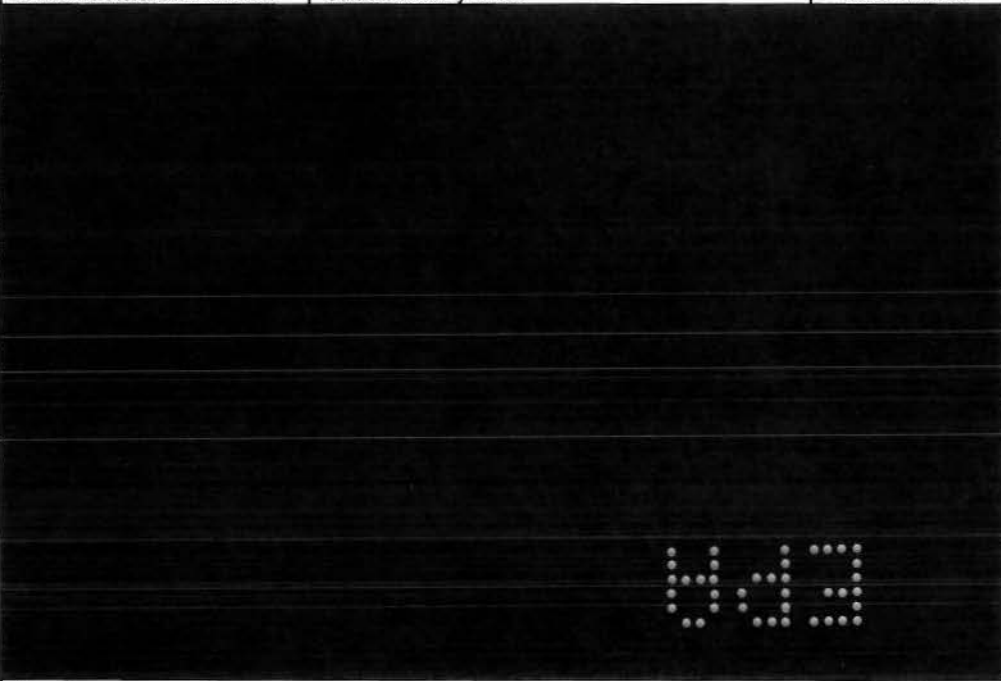

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
Signature			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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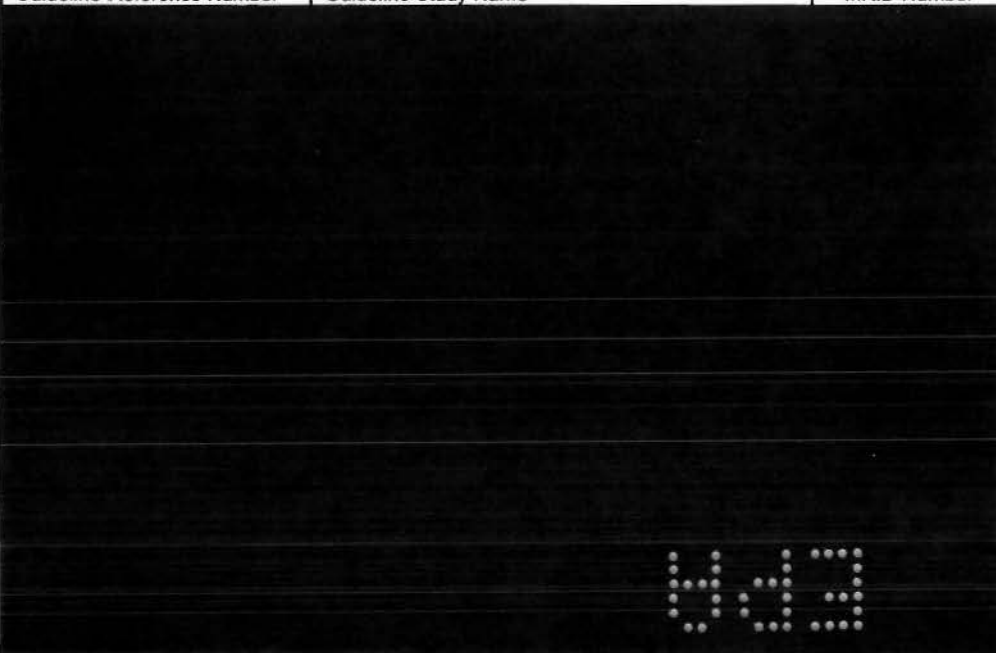
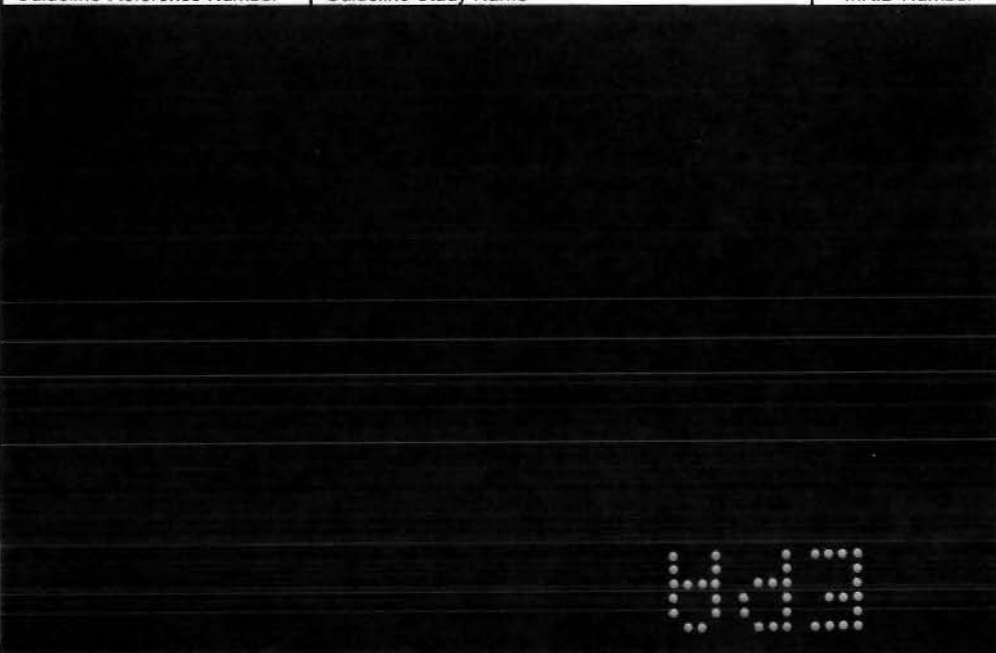
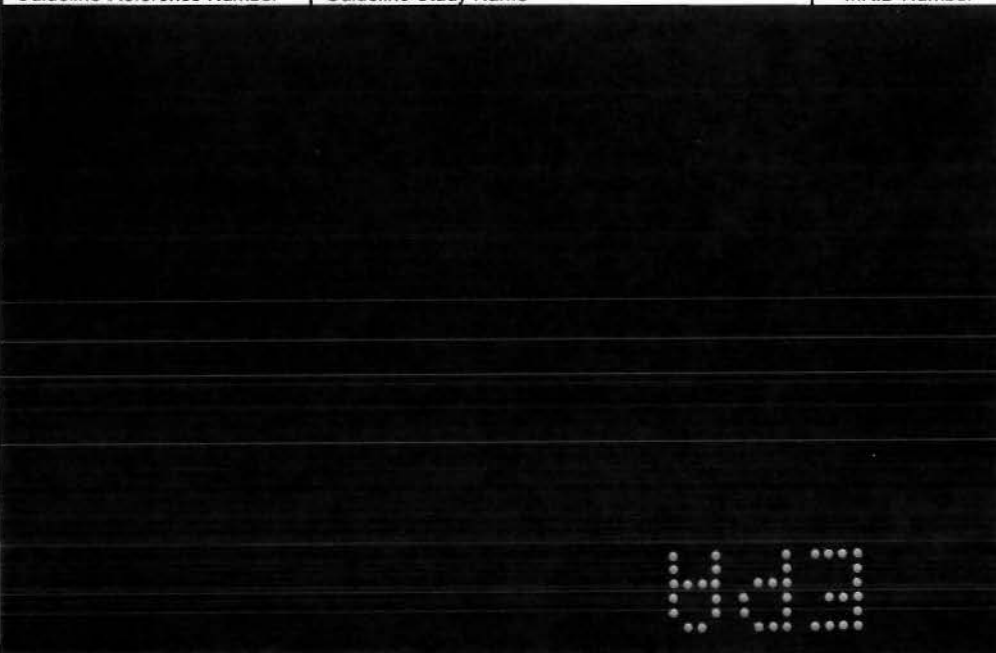

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
Signature			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t. Cry3Bb1* protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment Waived in BRAD
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment Granted in BRAD
			Monsanto Company	OWN	Benefits
			Monsanto Company	OWN	Benefits
Signature			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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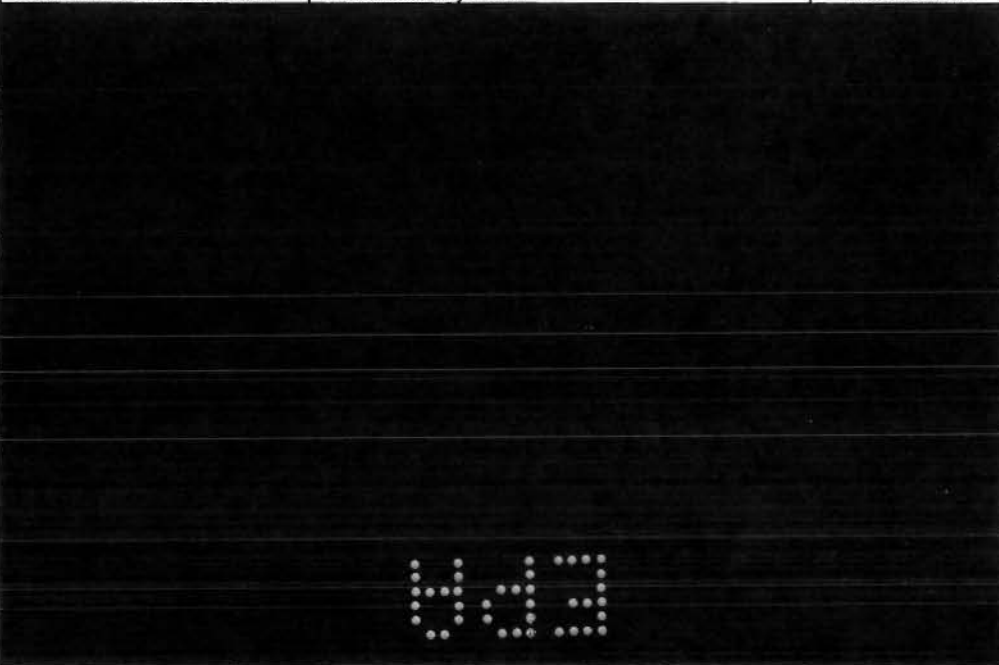
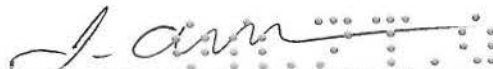
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Benefits
			Monsanto Company	OWN	Benefits
			Monsanto Company	OWN	Benefits
			Monsanto Company	OWN	Benefits
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			Monsanto Company	OWN	Benefits/IRM
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Date: June 11, 2008			EPA Reg. No./File Symbol: 524-551		Page 40 of 56
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 88017		
Ingredient <i>B.t.</i> Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	IRM
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008

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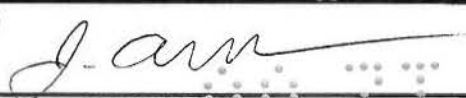


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Date: June 11, 2008		EPA Reg. No./File Symbol: 524-551		Page 41 of 56	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 88017			
Ingredient <i>B.t.</i> Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	Tolerance Exemption
			Monsanto Company	OWN	Tolerance Exemption
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008

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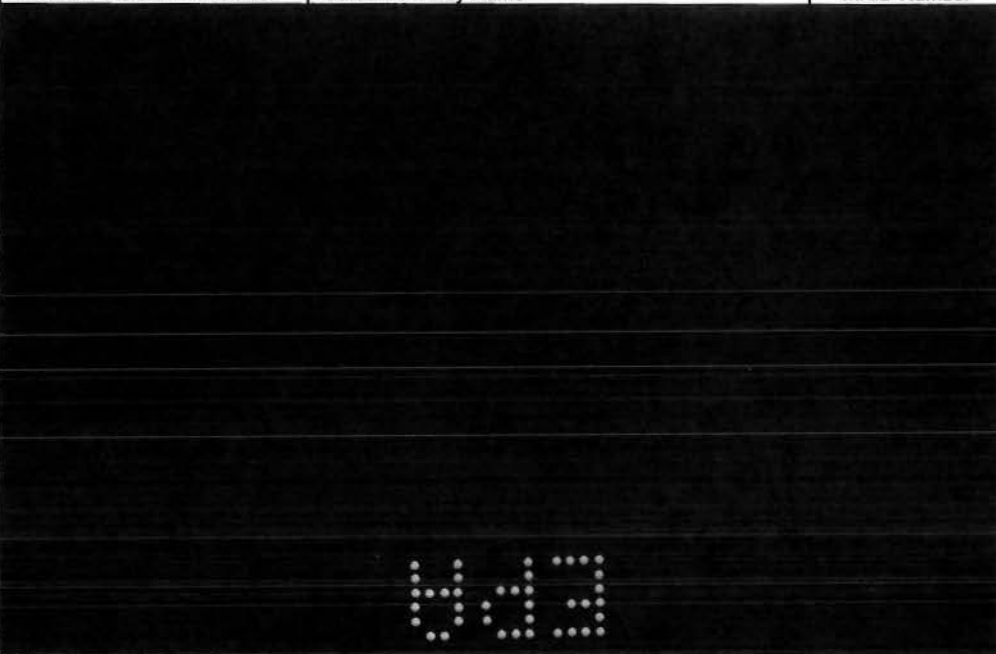
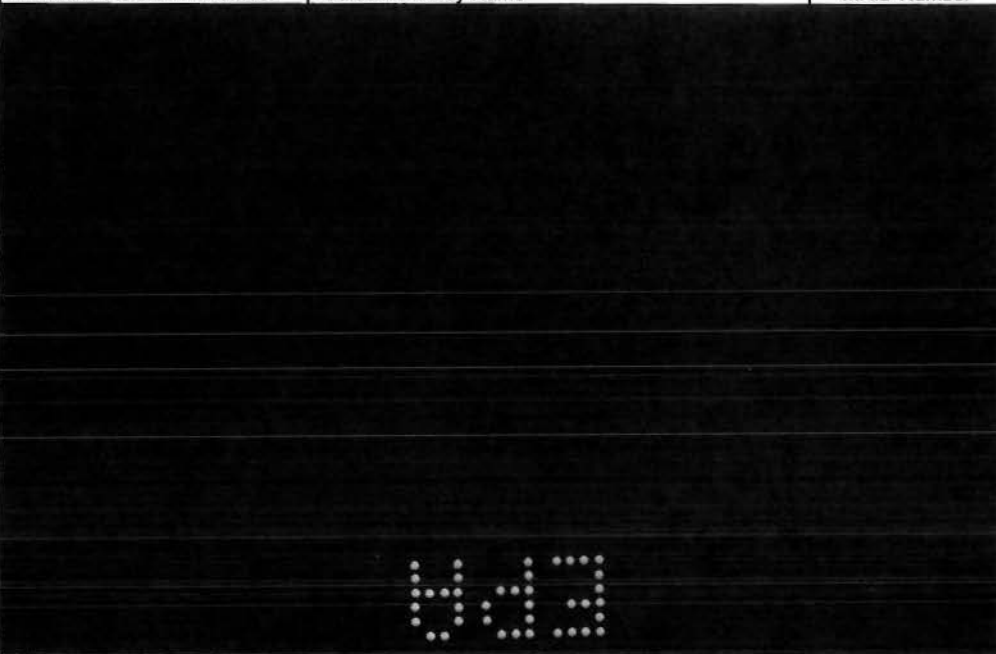
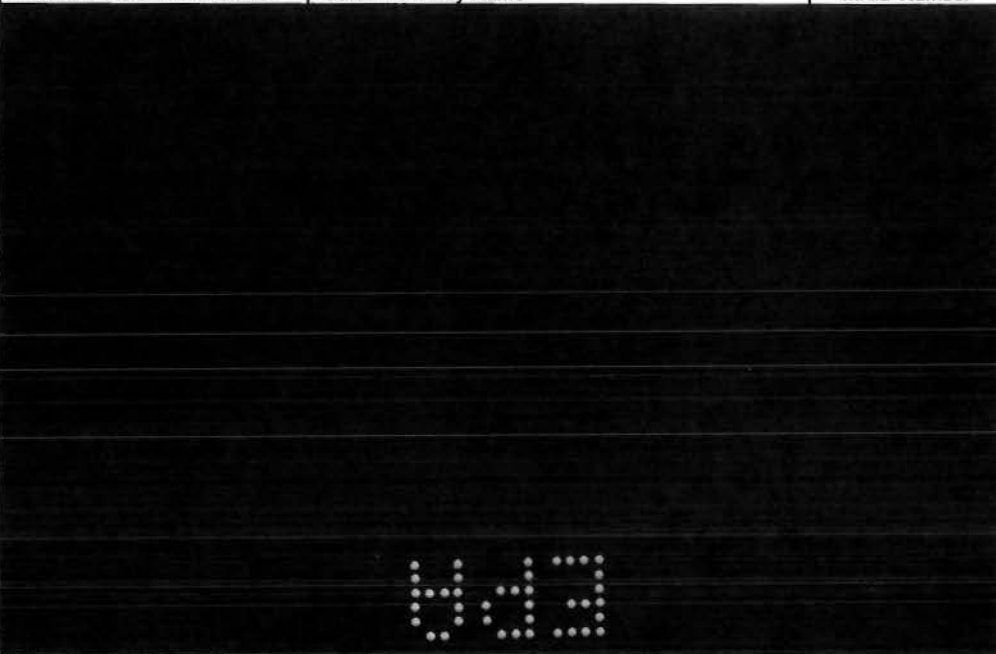
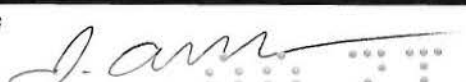
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t. Cry3Bb1* protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Tolerance Exemption
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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Monsanto Company

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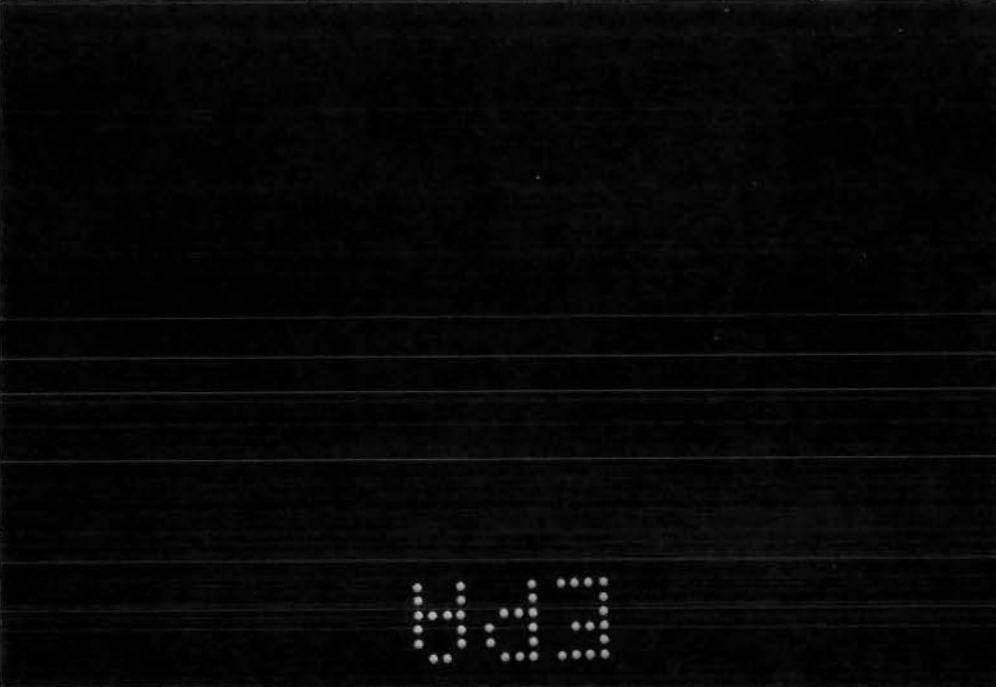
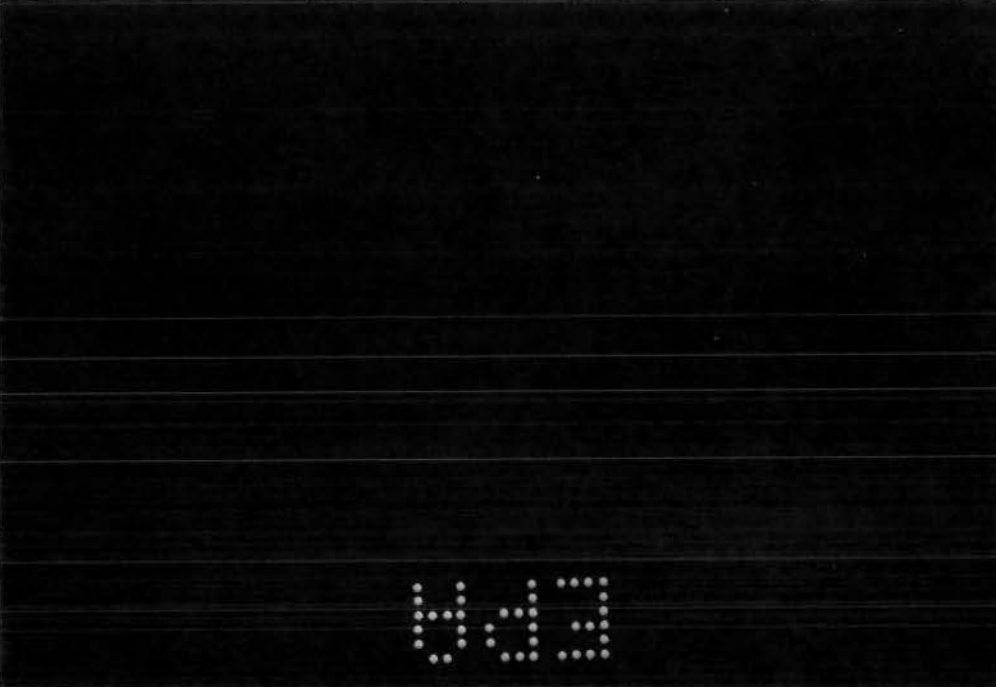
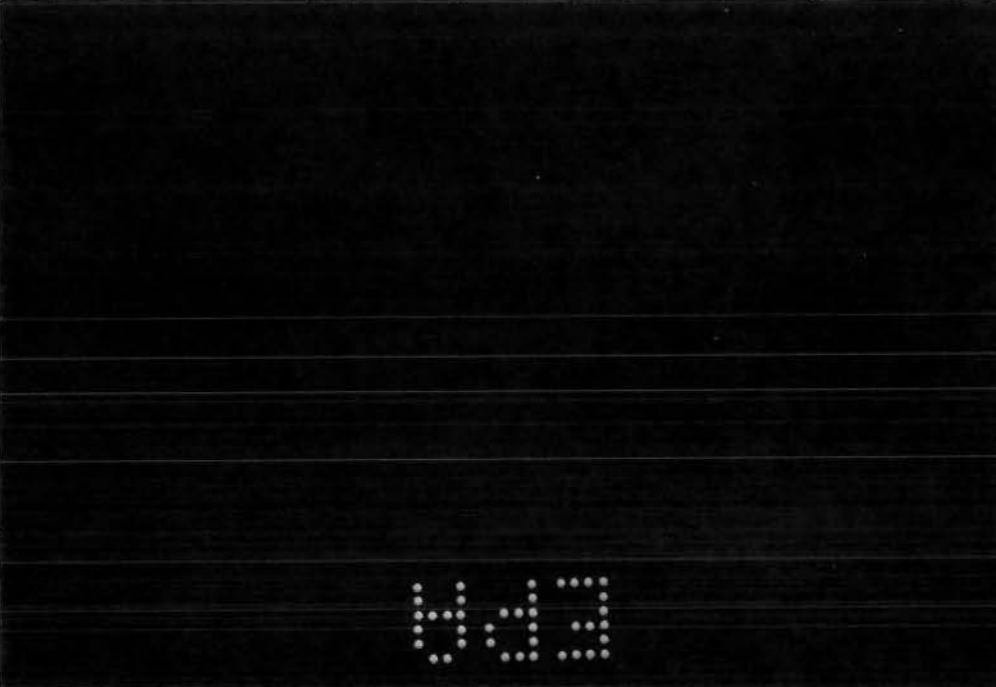


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Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167
Product: MON 88017
Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008

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Date: June 11, 2008

EPA Reg. No./File Symbol: 524-551



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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OW	Terms & Conditions
			Monsanto Company	OWN	Terms & Conditions
			Monsanto Company	OWN	Terms & Conditions
			Monsanto Company	OWN	Terms & Conditions
Signature			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008

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Date: June 11, 2008			EPA Reg. No./File Symbol: 68467-5		Page 45 of 56
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® RW Insect Protection		
Ingredient <i>B.t. Cry34/35Ab1</i> Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008

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DATA MATRIX

Date: June 11, 2008

EPA Reg. No./File Symbol: 68467-5


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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient *B.t. Cry34/35Ab1* Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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DATA MATRIX

Date: June 11, 2008


EPA Reg. No./File Symbol: 68467-5

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW *Insect Protection*Ingredient *B.t. Cry34/35Ab1* Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
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			68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date June 11, 2008	

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DATA MATRIX

Date: June 11, 2008

EPA Reg. No./File Symbol: 68467-5

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient B.t. Cry34/35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
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			68467	PER	

Signature

Name and Title
J. Austin Burns, Ph.D.
Regulatory Affairs ManagerDate
June 11, 2008

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Date: June 11, 2008			EPA Reg. No./File Symbol: 68467-5		Page 49 of 56
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® RW Insect Protection		
Ingredient <i>B.t. Cry34/35Ab1</i> Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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			68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date June 11, 2008

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW *Insect Protection*

Ingredient *B.t. Cry34/35Ab1* Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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			68467	PER	
			68467	PER	
			68467	PER	

Signature

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Regulatory Affairs Manager

Date
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Date: June 11, 2008

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient *B.t. Cry34/35Ab1* Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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			68467	PER	
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Date: June 11, 2008

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient *B.t. Cry34/35Ab1* Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
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			68467	PER	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient *B.t. Cry34/35Ab1* Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient *B.t. Cry34/35Ab1* Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient *B.t. Cry34/35Ab1* Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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Signature

Name and Title
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Regulatory Affairs Manager

Date
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Date: June 11, 2008

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW *Insect Protection*

Ingredient *B.t. Cry34/35Ab1* Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	

Signature

Name and Title
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SECTION II

SUMMARY OF THE APPLICATION

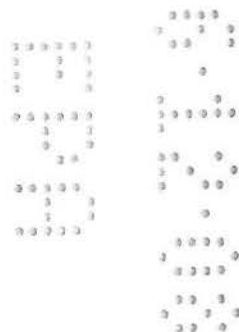
A health and environmental assessment of the Cry1A.105, Cry2Ab2, Cry3Bb1, Cry1F, Cry34/35Ab1 proteins produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, as well as the product benefits, are provided in Volume 2 of this application. Studies supporting product characterization and protein safety are provided in Volumes 3, 3a, 3b, 4, 4a, and 4b along with additional studies and information cited in the data matrix. Protein Interaction studies are presented in Volume 5, 5a, and 5b. An insect resistance management (IRM) plan and endangered species risk assessment are provided in Volumes 6 and 7, respectively. A non-target organism study is presented in Volumes 8 along with additional studies and information cited in the data matrix.

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SECTION III

PRODUCT LABEL

The subject of this application is for the *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry34Ab2, and Cry34/35Ab1 proteins and the genetic materials (PV-ZMIR245, PV-ZMIR39, PHP8999, PHP17662) necessary for their production in field corn containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7. A full and unrestricted FIFRA section 3 registration is being sought to support commercialization of this product. Five copies of the proposed label for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 are attached.



Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

Insect-Protected, Herbicide-Tolerant Corn

(OECD Unique Identifier: MON-89034-3 × DAS- 01507-1 × MON-88017-3 ×
DAS-59122-7)

Active Ingredients:

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034.....≤ 0.0026%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034≤ 0.0053%*

Bacillus thuringiensis Cry1F protein and the genetic material necessary (vector PHP8999) for its production in corn event TC1507≤ 0.0012%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017.....≤ 0.0079%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material necessary (vector PHP17662) for its production in corn event DAS-59122-7..... ≤ 0.0194%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material necessary (vector PHP17662) for its production in corn event DAS-59122-7..... ≤ 0.0042%*

Inert Ingredients:

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017≤ 0.0052%*

PAT protein (phosphinothricin acetyl transferase) and the genetic material necessary (vectors PHP17622 and PHP8999) for its production in corn event TC1507 and DAS-59122-7..≤ 0.00045%*

*Maximum percent (wt/wt) of dry forage

CAUTION

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS_____

255

EPA Registration No. 524-xxx

EPA Establishment No. 524-MO-002

EPA Establishment No. 029964-IA-001

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling. Information regarding commercial production must be included in the Technology Use Guide.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 protects corn crops from leaf, stalk, and ear damage caused by corn borers and root damage caused by corn rootworm larvae. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 corn, an insect resistance management plan must be implemented which includes planting of a structured refuge. Growers who fail to comply with the IRM requirements risk losing access to Monsanto's corn PIP products.

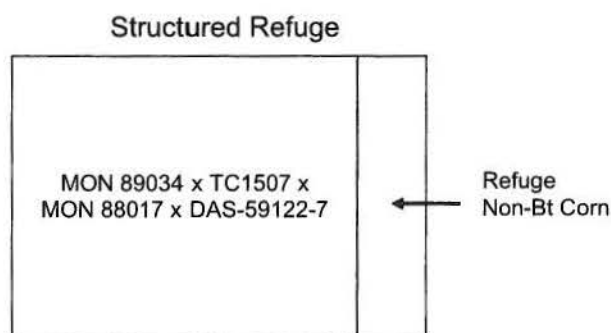
These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn and small scale research trials for observation.

Several options for deployment of the refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 are available to growers. These options are based on the planting of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in cotton or non-cotton growing regions and the insect pressure present in those locations. The refuge sizes for these regions are either 5% (i.e. 5 acres of non-Bt corn for every 95 acres MON 89034 × TC1507 × MON 88017 × DAS-59122-7 planted) or 20% (20 acres of non-Bt corn for every 80 acres of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 planted), and are presented in the table below:

Region	Refuge size	In-field or adjacent refuge	Refuge separated by up to ½ mile
Cotton belt where CEW is a significant pest and WCRW, NCRW and MCRW are not significant: NC, SC, GA, FL, TN, AL, MS, LA, AR, northern TX	20% non-Bt corn	Yes	Yes
Cotton belt where CEW is a significant pest and MCRW is significant: southern TX	20% non-Bt corn	Yes	No

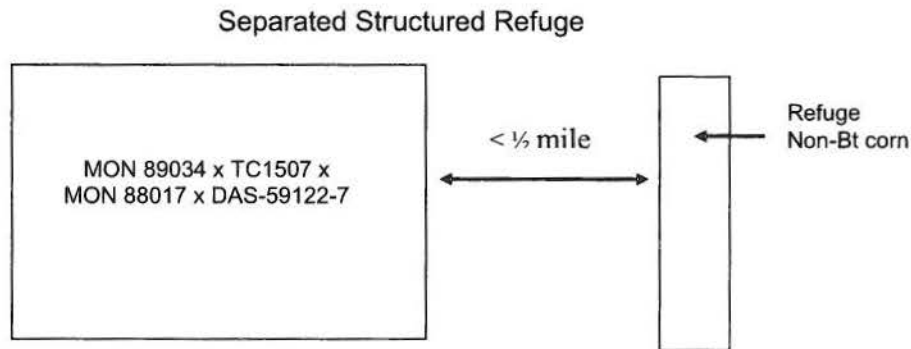
Cotton belt where CEW is not a significant pest and WCRW, NCRW and MCRW are not significant: NM, AZ, CA, NV	5% non-Bt corn	Yes	Yes
Non-cotton states where WCRW, NCRW and MCRW are not significant: OR, WA, ID, MT, WY, UT, CO, OK, VA, WV, PA, MD, DE, CT, RI, NJ, NY, ME, MA, NH, VT, HI, AK			
Non-cotton-growing where WCRW, NCRW and/or MCRW are significant: KS, NE, SD, ND, MN, IA, MO, IL, WI, MI, IN, OH, KY	5% non-Bt corn	Yes	No

If corn rootworms are significant within a region, the structured refuge must be planted as an in-field or adjacent refuge using corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. It can be planted as a block within or adjacent (e.g., across the road) to the MON 89034 × TC1507 × MON 88017 × DAS-59122-7, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control should be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). A schematic of one common refuge deployment option is shown below:



If corn rootworms are not significant within a region, the structured refuge may be planted as an in-field or adjacent refuge, or as a separate block that is within ½ mile of the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 field. The structured refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn borers or corn

rootworms. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). A schematic of one refuge option with the refuge planted within a ½ mile of the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 field is shown below:



Corn Insects Controlled or Suppressed

European corn borer (ECB)	<i>Ostrinia nubilalis</i>
Southwestern corn borer (SWCB)	<i>Diatraea grandiosella</i>
Southern cornstalk borer (SCSB)	<i>Diatraea crambidoides</i>
Corn earworm (CEW)	<i>Helicoverpa zea</i>
Fall armyworm (FAW)	<i>Spodoptera frugiperda</i>
Stalk borer	<i>Papaipema nebris</i>
Lesser corn stalk borer	<i>Elasmopalpus lignosellus</i>
Sugarcane borer (SCB)	<i>Diatraea saccharalis</i>
Western bean cutworm (WBC)	<i>Richia albicosta</i>
Black cutworm	<i>Agrotis ipsilon</i>
Western corn rootworm (WCRW)	<i>Diabrotica virgifera virgifera</i>
Northern corn rootworm (NCRW)	<i>Diabrotica barberi</i>
Mexican corn rootworm (MCRW)	<i>Diabrotica virgifera zeae</i>

Sales of corn hybrids that contain Monsanto's Bt corn plant pesticide must be accompanied by a Grower Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

Insect-Protected, Herbicide-Tolerant Corn

(OECD Unique Identifier: MON-89034-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 ×
DAS-59122-7)

Active Ingredients:

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034.....≤ 0.0026%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034≤ 0.0053%*

Bacillus thuringiensis Cry1F protein and the genetic material necessary (vector PHP8999) for its production in corn event TC1507≤ 0.0012%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017.....≤ 0.0079%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material necessary (vector PHP17662) for its production in corn event DAS-59122-7..... ≤ 0.0194%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material necessary (vector PHP17662) for its production in corn event DAS-59122-7..... ≤ 0.0042%*

Inert Ingredients:

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017≤ 0.0052%*

PAT protein (phosphinothricin acetyl transferase) and the genetic material necessary (vectors PHP17622 and PHP8999) for its production in corn event TC1507 and DAS-59122-7..≤ 0.00045%*

*Maximum percent (wt/wt) of dry forage

CAUTION

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS _____

EPA Registration No. 524-xxx

EPA Establishment No. 524-MO-002

EPA Establishment No. 029964-IA-001

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling. Information regarding commercial production must be included in the Technology Use Guide.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 protects corn crops from leaf, stalk, and ear damage caused by corn borers and root damage caused by corn rootworm larvae. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 corn, an insect resistance management plan must be implemented which includes planting of a structured refuge. Growers who fail to comply with the IRM requirements risk losing access to Monsanto's corn PIP products.

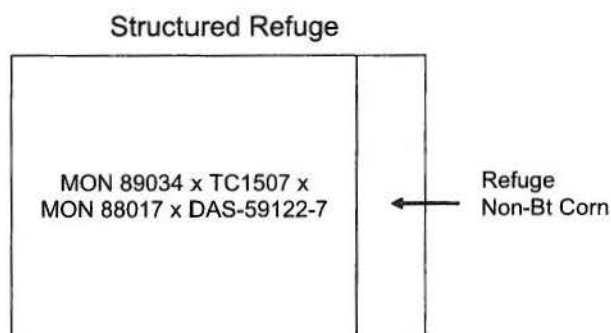
These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn and small scale research trials for observation.

Several options for deployment of the refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 are available to growers. These options are based on the planting of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in cotton or non-cotton growing regions and the insect pressure present in those locations. The refuge sizes for these regions are either 5% (i.e. 5 acres of non-Bt corn for every 95 acres MON 89034 × TC1507 × MON 88017 × DAS-59122-7 planted) or 20% (20 acres of non-Bt corn for every 80 acres of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 planted), and are presented in the table below:

Region	Refuge size	In-field or adjacent refuge	Refuge separated by up to ½ mile
Cotton belt where CEW is a significant pest and WCRW, NCRW and MCRW are not significant: NC, SC, GA, FL, TN, AL, MS, LA, AR, northern TX	20% non-Bt corn	Yes	Yes
Cotton belt where CEW is a significant pest and MCRW is significant: southern TX	20% non-Bt corn	Yes	No

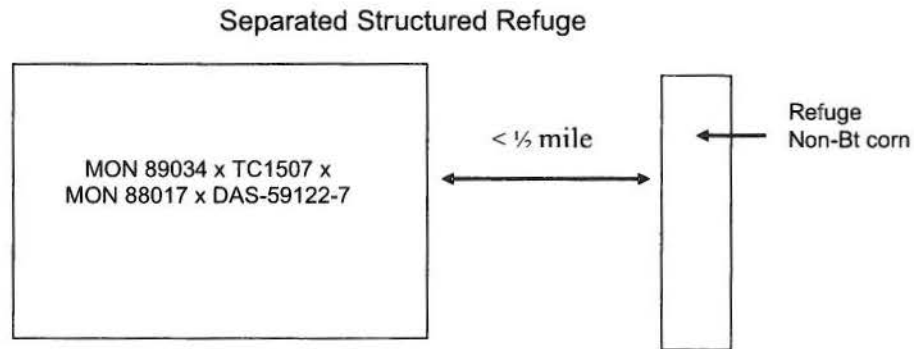
Cotton belt where CEW is not a significant pest and WCRW, NCRW and MCRW are not significant: NM, AZ, CA, NV	5% non-Bt corn	Yes	Yes
Non-cotton states where WCRW, NCRW and MCRW are not significant: OR, WA, ID, MT, WY, UT, CO, OK, VA, WV, PA, MD, DE, CT, RI, NJ, NY, ME, MA, NH, VT, HI, AK			
Non-cotton-growing where WCRW, NCRW and/or MCRW are significant: KS, NE, SD, ND, MN, IA, MO, IL, WI, MI, IN, OH, KY	5% non-Bt corn	Yes	No

If corn rootworms are significant within a region, the structured refuge must be planted as an in-field or adjacent refuge using corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. It can be planted as a block within or adjacent (e.g., across the road) to the MON 89034 × TC1507 × MON 88017 × DAS-59122-7, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control should be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). A schematic of one common refuge deployment option is shown below:



If corn rootworms are not significant within a region, the structured refuge may be planted as an in-field or adjacent refuge, or as a separate block that is within ½ mile of the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 field. The structured refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn borers or corn

rootworms. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). A schematic of one refuge option with the refuge planted within a ½ mile of the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 field is shown below:



Corn Insects Controlled or Suppressed

European corn borer (ECB)	<i>Ostrinia nubilalis</i>
Southwestern corn borer (SWCB)	<i>Diatraea grandiosella</i>
Southern cornstalk borer (SCSB)	<i>Diatraea crambidoides</i>
Corn earworm (CEW)	<i>Helicoverpa zea</i>
Fall armyworm (FAW)	<i>Spodoptera frugiperda</i>
Stalk borer	<i>Papaipema nebris</i>
Lesser corn stalk borer	<i>Elasmopalpus lignosellus</i>
Sugarcane borer (SCB)	<i>Diatraea saccharalis</i>
Western bean cutworm (WBC)	<i>Richia albicosta</i>
Black cutworm	<i>Agrotis ipsilon</i>
Western corn rootworm (WCRW)	<i>Diabrotica virgifera virgifera</i>
Northern corn rootworm (NCRW)	<i>Diabrotica barberi</i>
Mexican corn rootworm (MCRW)	<i>Diabrotica virgifera zeae</i>

Sales of corn hybrids that contain Monsanto's Bt corn plant pesticide must be accompanied by a Grower Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

Insect-Protected, Herbicide-Tolerant Corn

(OECD Unique Identifier: MON-89034-3 × DAS-01507-1 × MON-88017-3 ×
DAS-59122-7)

Active Ingredients:

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034.....≤ 0.0026%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034≤ 0.0053%*

Bacillus thuringiensis Cry1F protein and the genetic material necessary (vector PHP8999) for its production in corn event TC1507≤ 0.0012%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017.....≤ 0.0079%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material necessary (vector PHP17662) for its production in corn event DAS-59122-7..... ≤ 0.0194%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material necessary (vector PHP17662) for its production in corn event DAS-59122-7..... ≤ 0.0042%*

Inert Ingredients:

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017≤ 0.0052%*

PAT protein (phosphinothricin acetyl transferase) and the genetic material necessary (vectors PHP17622 and PHP8999) for its production in corn event TC1507 and DAS-59122-7..≤ 0.00045%*

*Maximum percent (wt/wt) of dry forage

CAUTION

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS _____

EPA Registration No. 524-xxx

EPA Establishment No. 524-MO-002

EPA Establishment No. 029964-IA-001

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling. Information regarding commercial production must be included in the Technology Use Guide.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 protects corn crops from leaf, stalk, and ear damage caused by corn borers and root damage caused by corn rootworm larvae. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 corn, an insect resistance management plan must be implemented which includes planting of a structured refuge. Growers who fail to comply with the IRM requirements risk losing access to Monsanto's corn PIP products.

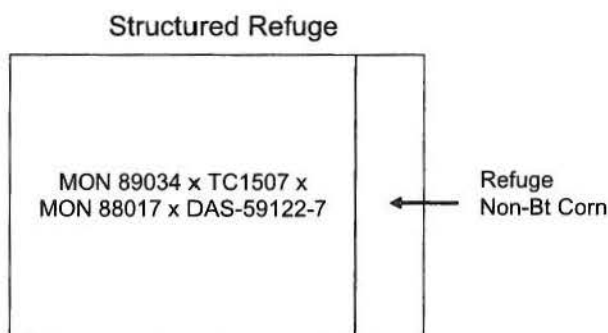
These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn and small scale research trials for observation.

Several options for deployment of the refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 are available to growers. These options are based on the planting of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in cotton or non-cotton growing regions and the insect pressure present in those locations. The refuge sizes for these regions are either 5% (i.e. 5 acres of non-Bt corn for every 95 acres MON 89034 × TC1507 × MON 88017 × DAS-59122-7 planted) or 20% (20 acres of non-Bt corn for every 80 acres of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 planted), and are presented in the table below:

Region	Refuge size	In-field or adjacent refuge	Refuge separated by up to ½ mile
Cotton belt where CEW is a significant pest and WCRW, NCRW and MCRW are not significant: NC, SC, GA, FL, TN, AL, MS, LA, AR, northern TX	20% non-Bt corn	Yes	Yes
Cotton belt where CEW is a significant pest and MCRW is significant: southern TX	20% non-Bt corn	Yes	No

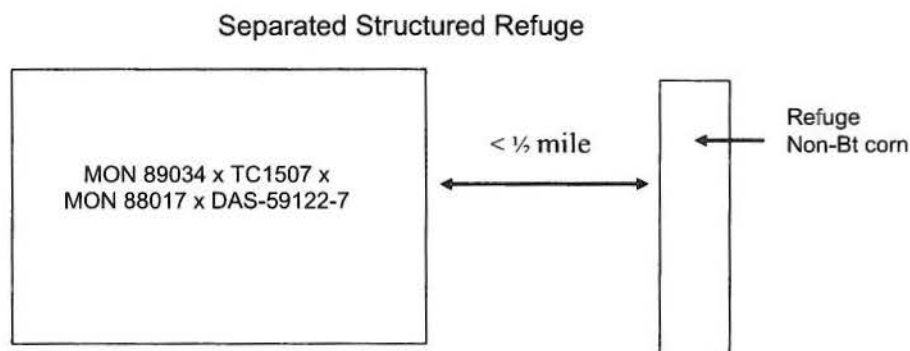
Cotton belt where CEW is not a significant pest and WCRW, NCRW and MCRW are not significant: NM, AZ, CA, NV	5% non-Bt corn	Yes	Yes
Non-cotton states where WCRW, NCRW and MCRW are not significant: OR, WA, ID, MT, WY, UT, CO, OK, VA, WV, PA, MD, DE, CT, RI, NJ, NY, ME, MA, NH, VT, HI, AK			
Non-cotton-growing where WCRW, NCRW and/or MCRW are significant: KS, NE, SD, ND, MN, IA, MO, IL, WI, MI, IN, OH, KY	5% non-Bt corn	Yes	No

If corn rootworms are significant within a region, the structured refuge must be planted as an in-field or adjacent refuge using corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. It can be planted as a block within or adjacent (e.g., across the road) to the MON 89034 × TC1507 × MON 88017 × DAS-59122-7, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control should be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). A schematic of one common refuge deployment option is shown below:



If corn rootworms are not significant within a region, the structured refuge may be planted as an in-field or adjacent refuge, or as a separate block that is within ½ mile of the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 field. The structured refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn borers or corn

rootworms. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). A schematic of one refuge option with the refuge planted within a ½ mile of the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 field is shown below:



Corn Insects Controlled or Suppressed

European corn borer (ECB)	<i>Ostrinia nubilalis</i>
Southwestern corn borer (SWCB)	<i>Diatraea grandiosella</i>
Southern cornstalk borer (SCSB)	<i>Diatraea crambidoides</i>
Corn earworm (CEW)	<i>Helicoverpa zea</i>
Fall armyworm (FAW)	<i>Spodoptera frugiperda</i>
Stalk borer	<i>Papaipema nebris</i>
Lesser corn stalk borer	<i>Elasmopalpus lignosellus</i>
Sugarcane borer (SCB)	<i>Diatraea saccharalis</i>
Western bean cutworm (WBC)	<i>Richia albicosta</i>
Black cutworm	<i>Agrotis ipsilon</i>
Western corn rootworm (WCRW)	<i>Diabrotica virgifera virgifera</i>
Northern corn rootworm (NCRW)	<i>Diabrotica barberi</i>
Mexican corn rootworm (MCRW)	<i>Diabrotica virgifera zea</i>

Sales of corn hybrids that contain Monsanto's Bt corn plant pesticide must be accompanied by a Grower Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

Insect-Protected, Herbicide-Tolerant Corn

(OECD Unique Identifier: MON-89034-3 × DAS-01507-1 × MON-88017-3 ×
DAS-59122-7)

Active Ingredients:

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*Maximum percent (wt/wt) of dry forage

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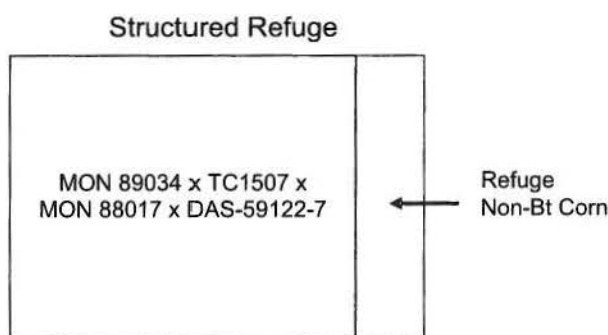
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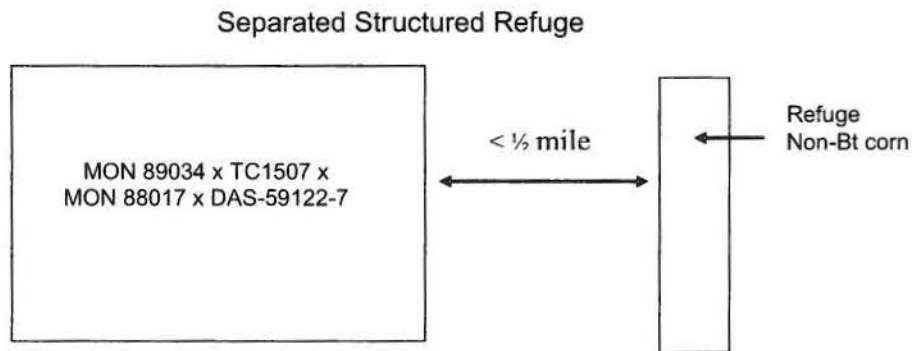
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If corn rootworms are significant within a region, the structured refuge must be planted as an in-field or adjacent refuge using corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. It can be planted as a block within or adjacent (e.g., across the road) to the MON 89034 × TC1507 × MON 88017 × DAS-59122-7, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control should be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). A schematic of one common refuge deployment option is shown below:



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 Lesser corn stalk borer
 Sugarcane borer (SCB)
 Western bean cutworm (WBC)
 Black cutworm

Ostrinia nubilalis
Diatraea grandiosella
Diatraea crambidoides
Helicoverpa zea
Spodoptera frugiperda
Papaipema nebris
Elasmopalpus lignosellus
Diatraea saccharalis
Richia albicosta
Agrotis ipsilon

Western corn rootworm (WCRW)
 Northern corn rootworm (NCRW)
 Mexican corn rootworm (MCRW)

Diabrotica virgifera virgifera
Diabrotica barberi
Diabrotica virgifera zea

Sales of corn hybrids that contain Monsanto's Bt corn plant pesticide must be accompanied by a Grower Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

SECTION IV

PRODUCT ANALYSIS

Studies and volumes listed in the data matrix included in this application describe the a) human health and environmental assessment of MON 89034 × TC1507 × MON 88017 × DAS-59122-7, b) the molecular identity of MON 89034 × TC1507 × MON 88017 × DAS-59122-7, and c) levels of the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 proteins produced in tissues of MON 89034 × TC1507 × MON 88017 × DAS-59122-7.

SECTION V

RESIDUE DATA

EPA has registered the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, and Cry34/Cry35Ab1 proteins as produced in corn. The safety of these proteins has been demonstrated and they are exempted from the requirement of a tolerance.

Protein	Tolerance Exemption Information		
	40 CFR	Date	Crop(s)
Cry1A.105	§174.502	2008	Corn
Cry1F	§174.520	2001	Corn
Cry2Ab2	§174.503	2008	Cotton and corn
Cry3Bb1	§174.518	2004	Corn
Cry34/ Cry35Ab1	§174.506	2005	Corn

SECTION VI

NONTARGET ORGANISM DATA

Studies conducted by Monsanto to characterize the potential hazards to nontarget organisms (NTOs) as a result of exposure to the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 proteins were previously submitted to the EPA, and are referenced by MRID in the data matrix. The environmental assessments of the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 proteins produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 are described in Volumes 2, 5, 7 and 8 of this application.

SECTION VII

TOXICOLOGY DATA

Studies conducted to assess the potential toxicity and allergenicity of the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins have previously been submitted to EPA and are referenced by MRID in the data matrix. Studies demonstrating functional equivalence of the *E. coli*- and plant-produced Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 proteins are referenced by MRID number in the data matrix.

SECTION VIII

EFFICACY DATA

Data demonstrating the efficacy of the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 proteins produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 are presented in Volume 6 of this application. The spectrums of insecticidal activity of the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 proteins are referenced by MRID in the data matrix. The proposed IRM plan for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is provided in Volume 6 of this application.

FOR OFFICIAL USE ONLY

200

FILE SYMBOL	524- LIR
REGISTRATION NO.	

CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE SUBMITTED	SUBMITTED BY (✓)	
	APPLICANT	BASIC SUPPLIER
JUN 12 2008		

**Do Not Write Comments,
Formula, or Parts of Formula
on This Envelope**

NOTE

It shall be unlawful—for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

Page _____ is not included in this copy.

Pages 277 through 286 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
 - ☐ Identity of product impurities.
 - ☐ Description of the product manufacturing process.
 - ☐ Description of quality control procedures.
 - ☐ Identity of the source of product ingredients.
 - ☐ Sales or other commercial/financial information.
 - ☐ A draft product label.
 - ☒ The product confidential statement of formula.
 - ☐ Information about a pending registration action.
 - ☐ FIFRA registration data.
 - ☐ The document is a duplicate of page(s) _____.
 - ☐ The document is not responsive to the request.
 - ☐ Proprietary information pertaining to the chemical composition of an inert ingredient provided by the source of the ingredient.
 - ☐ Attorney-Client Privilege.
 - ☐ Claimed Confidential by submitter upon submission to the Agency.
 - ☐ Internal Deliberative Information.
-

* The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
